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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Alok Nigam )  
Serial No.: To Be Determined ) Art Unit: To Be Determined  
Filed: Herewith, November 1, 2000 ) Examiner: To Be Determined  
For: Sutureless Implantable Device and )  
Method for Treatment of Glaucoma )

Transmittal of a Continuation Utility Patent Application

Express Mail mailing label no. EL636155181US

Box Patent Application  
Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Transmitted herewith for filing is continuation utility patent application for "Sutureless Implantable Device and Method for Treatment of Glaucoma."

The applicant(s) hereby request(s) the filing of the continuatin patent application under 37 CFR §1.60, corresponding to copending application Serial No. 09/123,676.

True copies of the following are enclosed:

the prior application as filed, including all forty eight (33) pages of the specification (including claims 1-21), an abstract of one (1) page, and all seven (7) sheets of formal drawings; and

the oath or declaration filed in the parent application, showing the signatures or an indication it was signed; and,

Please delete the names of the following persons who are not inventors of the invention being claimed in this continuation/divisional application:

- [ X ] Please amend the specification after the granting of a filing date herein by deleting the paragraph under the heading "Related Applications", and substituting therefore: --This patent application is a continuation of application Serial No. 09/123,676 filed on July 27, 1998, which was a continuation-in-part of Serial No. 08/738,332 filed on October 25, 1996 and is now issued as United States Patent No. 6,007,510.--
- [X] Kindly enter in this continuational/divisional application the following preliminary amendment, prior to calculation of the required filing fee:

**IN THE CLAIMS:**

**Please cancel claims 1-17, without prejudice.**

- [ ] Check No. [Check No.] covering the filing fee in the amount of \$[Check amount] accompanies this application, calculated as follows:

For Basic fee	(Col. 1) No. Filed	(Col. 2) No. extra	Small entity			Other than a Small entity	
			Rate	Fee	Or	Rate	Fee
Total claims	4 - 20 =	0	x 9	\$ 0	Or	x 18	\$
Indep claims	1 - 3 =	0	x 40	\$ 0	Or	x 80	\$
_ Multiple dependent claims presented		N/A	+ 135	\$ 0	Or	+ 270	\$
			Total	\$ 0	Or	Total	\$

- [ X ] An Assignment of the invention to Anamed, Inc.. was previously executed and is recorded in the United States Patent Office at Reel 9347/Frame 0335.
- [ ] A Certificate of Ownership under 37 CFR 3.73 (b) and Power of Attorney.
- [ X ] Formal drawings are enclosed.
- [ X ] The undersigned is the Applicant's attorney of record in the prior application, and all future communications should be addressed to the undersigned.
- [ X ] The statement(s) of Small Entity Status filed in the prior application is (are) still proper.
- [ X ] An information disclosure statement was filed in relation to the parent case.

A check in payment of the required small entity filing fee and a signed Power of Attorney will be submitted in response to a Notice to File Missing Parts (Filing Date Granted), which should be mailed to applicant's undersigned counsel at the address shown:

Respectfully submitted,

STOUT, UXA, BUYAN & MULLINS, LLP

Date: November 1, 2000



Robert D. Buyan, Reg. No. Reg. No. 32,460

4 Venture, Suite 300  
Irvine, CA 92618  
Telephone: (949) 450-1750  
Facsimile: (949) 450-1764  
Email: [rbuyan@patlawyers.com](mailto:rbuyan@patlawyers.com)

U.S. PATENT AND TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Alok Nigam )  
Application No.: Unassigned ) Art Unit: Unassigned  
Filed: Herewith, November 1, 2000 )  
For: Sutureless Implantable Device and ) Examiner: Unassigned  
Method for Treatment of Glaucoma )

Express Mail Mailing Label No. EL636155181US

Box Patent Application  
Commissioner for Patents  
Washington, D.C. 20231

CERTIFICATE OF MAILING

Dear Sir:

I hereby certify that a Continuation application for a patent consisting of a specification (34 pages), 7 sheets of drawings, Transmittal Letter with Amendment and return postcard are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on November 1, 2000 and is addressed to Box PATENT APPLICATION, Commissioner for Patents, Washington, D.C. 20231.

Respectfully submitted,

Stout, Uxa, Buyan & Mullins, LLP

Date: November 1, 2000

  
Annette Brooks, Assistant

4 Venture, Suite 300  
Irvine, CA 92618  
Telephone: (949) 450-1750, Facsimile: (949) 450-1764  
email: rbuyan@patlawyers.com

# SUTURELESS IMPLANTABLE DEVICE AND METHOD FOR TREATMENT OF GLAUCOMA

## Related Application

5        This application is a continuation-in-part of United States Patent Application Serial No. 08/738,332 filed October 25, 1996 entitled "Implantable Devices and Methods for Controlling the Flow of Fluids Within the Body."

## Field of the Invention

10      The present invention relates generally to medical apparatus and methods, and more particularly to a device which is implantable in a mammalian body to control the pressure of fluid within a body cavity by shunting such fluid to another site within the body, when the fluid pressure within the body cavity reaches a pre-determined level.

## Background of the Invention

15      A number of diseases and disorders in humans and other mammals are characterized by the build-up of excessive fluid pressure within one or more body cavities. In many instances, implantable devices or surgical procedures may be used to shunt excessive fluid from the body cavity wherein the excessive pressure build up is present, to one or more other sites within the body, as a means of receiving the undesirable pressure buildup, and thereby deterring the development of undesirable sequelae which may result from such pressure build-up.

### i. Glaucoma

25      Glaucoma is a disease of the eye which is characterized by high intraocular pressure, and is among the leading causes of blindness in the world. In general, glaucoma results from a defect in the functional drainage system, whereby naturally occurring endogenous fluid (e.g., aqueous humor) is drained from the interior of the eye. The result of this decreased functional drainage of

the eye is three-fold: a) increased intraocular pressure, b) degeneration of the optic nerve and supporting tissue at the optic nerve head (disk), and c) progressive loss of the visual field.

Individual cases of glaucoma are generally classified, on the basis of  
5 etiology, into two categories. These two major are "closed angle glaucoma" and  
"open angle glaucoma".

In closed angle glaucoma (*syn. "angle-closure glaucoma", "narrow-angle glaucoma", "pupillary block glaucoma"*) excessive fluid accumulates within the anterior chamber of the eye due to the gradual closure of an anterior angle  
10 formed by the junction of the iris and the inner surface of the trabecular mesh work through which the aqueous humor is normally reabsorbed. Closure of this anatomical angle prevents normal drainage of aqueous humor from the anterior chamber of the eye.

In open angle glaucoma (*syn. "chronic simple glaucoma" "simple glaucoma", "wide-angle glaucoma"*) the angle of the anterior chamber remains normal, but the drainage of aqueous humor from the anterior chamber is impeded or blocked by other means, such as edema or swelling of the trabecular spaces, abnormal pigment dispersion, or non-perforating injury to the eye resulting in vascular congestion.  
15

Various pharmacologic modes of treatment have been used to lessen the intraocular fluid pressure in glaucoma patients. Drugs which have been administered to treat glaucoma have included parasympathomimetic agents of the choline ester type (e.g., bethanechol, carbachol and methacholine), carbonic anhydrase inhibitors (e.g., acetazolamide), anticholinesterase agents (e.g.,  
20 physostigmine, pilocarpine, demecarium, echothiophate and isofluorophate), sympathomimetic agents (e.g, epinephrine, phenylephrine) and  $\beta$ -adrenergic blocking agents (e.g., timolol). However, these various drug therapies for glaucoma are sometimes associated with significant untoward effects, including headache, blurred vision, allergic reactions, retinal detachment, phacodinesis,  
25

histological changes within the eye and potential interactions with other drugs.

As an alternative to pharmacologic modes of therapy, at least some glaucoma patients may be treated surgically by creating surgical openings into the anterior chamber of the eye, to facilitate drainage of excess aqueous humor from the anterior chamber. Many of these surgical techniques involve the formation of an opening or hole into the anterior chamber, under the conjunctiva and/or scleral flap such that fluid will be drained by filtration from the anterior chamber of the eye, into the tissues located within the lateral wall of the eye.

The major problems associated with these surgical filtration procedures stem

from the size of the opening or hole made into the anterior chamber. These problems include hypotony, synechiae, inflammation, cataract, corneal decompensation (edema), vitritis, choroidal separation (detachment), macular edema, and infections which may cause endophthalmitis. Moreover, such glaucoma filtration surgery is often unsuccessful due to the formation of dense

fibrovascular connective tissue (e.g., scar tissue) around the surgical opening formed into the anterior chamber. Such proliferation of connective tissue tends to close off the surgically-formed opening into the anterior chamber, thereby deterring or preventing the desired filtration of aqueous humor into the subconjunctival space.

In view of post-surgical complications associated with the development of fibrovascular connective tissue (e.g., scar tissue) around the surgical site, a number of implantable drainage devices have been used to ensure that the desired filtration and outflow of aqueous humor through the surgically-formed opening will continue, despite the formations of, scar tissue during the post

operative period. Examples of implantable shunts or other implantable apparatus which have previously been implanted into the eye for drainage of aqueous humor from the anterior chamber of the eye include those described in United States Patent Nos. 4,750,901 (Molteno), 5,041,081 (Odrich), 5,476,445 (Baerveldt), 4,886,488 (White), 5,454,796 (Krupin), 5,397,300

(Baerveldt), 5,372,577 (Ungerleider), 5,338,291 (Speckman, et al.), 5,300,020 (L'Esperance), 5,178,604 (Baerveldt, et al.), 5,171,213 (Price), 5,092,837 (Klein et al.), 4,968,296 (Klein et al.), 4,946,436 (Smith), 4,936,825 (Ungerleider), 4,886,488 (White), 4,806,382 (Burns et al.), 4,554,918 (White), 4,521,210 5 (Wong), 4,428,746 (Mendez), 4,184,491 (McGannon), 4,157,718 (Baehr), 4,030,480 (Meyer), 5,433,701 (Rubinstein), 5,346,464 (Camras), 5,073,163 (Lippman), 4,604,087 (Joseph), 5,180,362 (Worst), 5,520,631 (Li et al.).

The major disadvantage associated with the use of implantable shunts for treatment of glaucoma is that, in the immediate post operative period, the 10 shunt may facilitate excessive fluid drainage which results in hypotony within the anterior chamber, flattening of the anterior chamber and potential choroidal detachment and/or phthisis bulbi. Such excessive post-operative fluid outflow may also result in expansion of the fibrous capsule located beneath the rectus muscles of the eye. Such expansion of the fibrous capsule can stretch and 15 tighten the rectus muscles, thereby inducing heterotropia and impairing the motility of the eye in the quadrant wherein the implant is located. Additionally, due to the size of some of these shunt devices, the bulky presence of the device itself within the subconjunctival space can cause scleral erosion, changes in the natural curvature of the eye, or damage to adjacent vasculature and tissue. 20 Other problems associated with the use of implantable shunt devices for the treatment of glaucoma involve friction and wear imparted by the implanted shunt device, irritation of the iris endothelium caused by insertion of the shunt device into the anterior chamber, and migration of microbes, cells, proteins or other matter through the lumen of the shunt device and into the anterior chamber of 25 the eye.

Also, the surgical procedures used to implant the prior art fluid shunting devices have typically been laborious in nature and have typically required that suturing of the fluid shunting device to the surrounding tissue of the host, to hold the fluid shunting device at its desired location within the eye. The installation

of sutures to anchor the implanted fluid shunting device is time consuming and, in cases where such sutures are not properly placed, can result in undesirable tugging, traction or stress on the surrounding tissue and/or disconfiguration of the implanted device. Also, the installation of such sutures can result in 5 unintentional, iatrogenic perforation of the anterior or posterior chamber of the eye, with resultant leakage of aqueous or vitreous humor and/or resultant cellular ingrowth and opacification of the aqueous and/or vitreous humor.

**ii. Hydrocephalus**

Another disorder in which the build-up of abnormal fluid pressure is a hallmark is hydrocephalus. In hydrocephalus, excessive amounts of cerebrospinal fluids accumulate within skull, generally resulting in elevated intracranial pressure. The chronic elevation in intracranial pressure caused by such excessive cerebrospinal fluid within the skull typically results in enlargement of the head, prominence of the forehead, brain atrophy, mental deterioration, and convulsions. Hydrocephalus is maybe of congenital origin or may be an acquired disease. In some patients, hydrocephalus is of sudden onset while in others it is slowly progressive.

In addition to various pharmacologic therapies, the surgical approach to treatment of hydrocephalus often involves the implantation of a shunt which facilitates drainage of excess cerebrospinal fluid from the intracranial space, to other areas of the body wherein it can be tolerated--most often into the peritoneal cavity. In addition to glaucoma and hydrocephalus, numerous other diseases and disorders involve the buildup of excessive fluid within one or more anatomical spaces (i.e., cavities) of the body, and may be effectively treated by 20 shunting of the excessive fluid from the affected body space (i.e., body cavity) to other region(s) of the body. However, in many cases, it is desirable that an implantable shunt device be used, and that such shunt device be valved or pressure-regulated such that only excessive fluid will be removed from the 25 affected body cavity, while allowing the normal amount of such fluid to remain

within the affected body cavity, so long as the pressure within the cavity is in the normal range. Thus, it is desirable for the implanted shunt device to include a pressure-sensitive opening or other pressure-actuated valving apparatus which will allow fluid to flow out of the affected body cavity only when the fluid within  
5 the body cavity has exceeded a predetermined maximum pressure.

One complication associated with the use of implantable shunt devices to drain fluid from body cavities is that proteins, cellular matter, or other debris may block the lumen of the shunt tube thereby interfering with the drainage of fluid through the tube. Also, proliferation of tissue or blebs may compress,  
10 collapse, or block the shunt tube. Moreover, pathogenic microorganism or irritating proteins or other matter may migrate through the lumen of the shunt tube into the affected body cavity in a manner which can lead to iatrogenic infection, irritation or inflammation of the affected body cavity.  
15

Given the above-summarized limitations and drawbacks associated with the implantable fluid-shunting devices of the prior art, it is apparent that no single fluid-shunting device has proven to be optimal for all applications. Accordingly, there exists a need in the art for the development for new implantable fluid-shunting devices which include: a) means for valving or pressure-regulation of the fluid outflow, b) means for preventing microbes, proteins, cells or other matter from clogging the shunt or migrating through the shunt in to the affected body cavity and/or c) means for anchoring the fluid-shunting device in its desired implanted position, without the need for suturing of the device to the adjacent tissue.  
20

#### Summary of the Invention

25 The present invention provides implantable devices for shunting or draining fluid from one intracorporeal location to another. In general, the implantable devices of the present invention comprise an elongate tube having a lumen extending longitudinally therethrough and a diffusion chamber mounted on the proximal end of the tube. The distal end of the tube is open, while the

proximal end of the tube is closed. A pressure-openable aperture is formed in a proximal portion of the tube which extends into the interior of the diffusion chamber. Such pressure-openable aperture will open when the pressure of fluid within the lumen of the tube exceeds a predetermined maximum pressure. In  
5 this manner, fluid will be permitted to flow from the distal end of the tube, through the lumen of the tube, through the pressure-openable aperture and into the interior of the diffusion chamber. Thereafter, such fluid may diffuse outwardly through the diffusion chamber and into the surrounding tissues or spaces of the body. The diffusion chamber is preferably formed of material  
10 which will prevent unwanted matter (e.g., proteins, solid particles greater than a predetermined size, or host cellular matter, such as tissues or individual cells), from entering the interior of the diffusion chamber and (a) interfering with the desired opening and closing of the pressure-openable aperture or (b) migrating through the lumen of the tube and into the region of the body adjacent the distal  
15 end of the tube.

In accordance with the invention, there are provided implantable devices which may be utilized for numerous fluid-shunting applications, including a) the treatment of glaucoma wherein aqueous humor is shunted from the anterior chamber of the eye and b) the treatment of hydrocephalus wherein  
20 cerebrospinal fluid is shunted from the intracranial space into another body cavity (e.g., the peritoneal cavity).

Further in accordance with the invention, there are provided fluid shunting devices which are implantable in the eye of a mammalian patient, within a subconjunctival pocket formed between two rectus muscles which are anatomically attached to the eye at spaced-apart locations, to control the pressure of fluid within the anterior chamber of the eye without the use of sutures to hold the device in its desired implanted position. A sutureless implantable device in accordance with this aspect of the invention may comprise  
25 a) a tube which has a proximal end, a distal end, a side wall, and a lumen

extending longitudinally therethrough, b) a diffusion chamber which has an inner cavity formed therewithin. The diffusion chamber of the device is mounted on the proximal end of the tube, such that fluid which enters the distal end of the tube may flow through the lumen of the tube and into the inner cavity of the diffusion chamber. The distal end of the tube is insertable into the anterior chamber of the eye while the diffusion chamber remains positioned within a subconjunctival pocket, posterior to the limbus. The diffusion chamber has a posterior portion which is wider than the distance between the locations at which the adjacent rectus muscles are attached to the eye, and an inter-muscular portion which is slightly narrower than the distance between the rectus muscle attachment points. Preferably, the diffusion chamber also has an anterior portion which like its posterior portion, is wider than the distance between the adjacent rectus muscle attachment points. Such preferred sizing and configuration of the diffusion chamber allows it to be implanted within the subconjunctival pocket with its inter-muscular portion between the rectus muscle attachment points, its anterior portion extending anterior to the rectus muscle attachment points, and its posterior portion extending posterior to the rectus muscle attachment points. When so implanted, the diffusion chamber will remain in substantially fixed position and will be prevented by its engagement with the adjacent rectus muscles from undergoing substantial migration or movement in the longitudinal or lateral directions, without the need for sutures to anchor the diffusion chamber in place. Also, the diffusion chamber may be formed in a generally concave configuration which is analogous to the contour of the ocular bulb, thereby allowing the device to fit easily upon the scleral floor of the subconjunctival pocket, with minimal outward protrusion or tenting of the conjunctival tissue, and minimal discomfort to the patient.

Further objects and advantages of the present invention will become apparent to those skilled in the art upon reading and understanding the following detailed description and the accompanying drawings.

### Brief Description of the Drawings

Figure 1 is a perspective view of one embodiment of an implantable fluid-shunting device of the present invention.

Figure 2 is a longitudinal sectional view through line 2-2 of Figure 1.

5       Figure 3 is an enlarged longitudinal sectional view of the proximal-most portion of the fluid-carrying tube component of the device of Figure 1.

Figure 4 is a cross-sectional view through line 4-4 of Figure 1.

10      Figure 5 is partial transverse sectional view through a portion of a human eye showing an implantable fluid shunting device of the present invention positioned therewithin to relieve excessive pressure within the anterior chamber of the eye.

Figure 6 is a schematic showing of a human body wherein an implantable fluid-shunting device of the present invention has been surgically installed to drain excessive cerebrospinal fluid from the brain to the peritoneal cavity.

15      Figures 7a-7g are partial perspective views of alternative embodiments of the implantable fluid-shunting device of the present invention.

Figure 8 is a perspective view of a sutureless implantable fluid shunting device of the present invention useable to control intraocular pressure in glaucoma patients.

20      Figure 9 is a longitudinal sectional view trough line 9-9 of Figure 8.

Figure 10 is a schematic showing of a human eye having the device of Figure 10 implanted therein using a sutureless implantation technique of the present invention.

25      Figure 11 is a top plan view of view of the preferred diffusion chamber configuration for the device shown in Figures 8-10.

Figure 12 is a top plan view of an alternative diffusion chamber configuration for the device shown in Figures 8-10.

Figure 13 is a flow diagram for a sutureless method for implanting a fluid shunting device of the type shown in Figure 9.

## **Detailed Description of the Preferred Embodiments**

The following detailed description, and the accompanying drawings to which it refers are provided for purposes of exemplifying and illustrating representative examples and embodiments of the invention only, and are not intended to limit the scope of the invention in any way. Indeed, no effort has been made to exhaustively illustrate and describe all possible embodiments and configurations in which the present invention may take physical form.

### **i. Construction and Configuration of the Fluid Shunting Device**

With reference to Figures 1-4, there is shown a first embodiment of an implantable fluid shunting device 10 comprising an elongate tube 12 having a lumen 14 extending longitudinally therethrough and a diffusion chamber 20 mounted on the proximal end thereof. The tube 12 has an open distal end 16, a closed proximal end 18 and a pressure openable aperture 30 which is located in a proximal portion PP of the tube 12 which extends into the interior of the diffusion chamber 20.

In this regard, the diffusion chamber 20 is mounted on the tube 12 such that the proximal portion PP of the tube 12 adjacent the proximal end 18 thereof, extends into the inner cavity 26 of the diffusion chamber 20. The diffusion chamber 20 is mounted in sealing contact upon the outer surface of the tube 12 such that fluid which flows out of the tube 12 into the inner cavity 26 of the diffusion chamber 20 will not freely leak therefrom. The diffusion chamber 20 is preferably formed of membranous material (e.g., permeable or semipermeable membrane material) which will permit the fluid which is desired to be drained by the tube 12 to flow from the inner cavity 26 of the diffusion chamber, outwardly and into the region of the body wherein the diffusion chamber 20 is positioned, while preventing predetermined types of unwanted matter (e.g., proteins, solid particles which are greater than a predetermined size, etc.) from passing inwardly through such membrane and into the inner cavity 26 of the diffusion chamber 20. Additionally, the material of the diffusion

chamber 20 will prevent host cellular matter (e.g., tissues or cells such as fibroblasts, endothelium, epithelium, blood cells) from invading (e.g., ingrowing or migrating) the outer surface or inner lumen of the tube 12 and/or the inner cavity 26 of the diffusion chamber 20.

- 5        In the particular embodiment shown in Figures 1-3, diffusion chamber 20 is constructed of an upper membrane wall 22a and lower membrane wall 22b. The upper and lower membrane walls 22a, 22b are sealed to one another at their edges to form a sealed perimeter flange 24. Such sealing of the upper and lower membrane walls 22a, 22b also forms a fluid-tight seal with the tube 12,  
10      while allowing the proximal portion PP of the tube 12 to extend into the inner cavity 26 of the diffusion chamber 22.

- In the embodiment shown in Figures 1-3, suture passage apertures 36 are formed in the diffusion chamber 20 to facilitate suturing of the device 10 at it's desired position within the body. Also, tissue ingrowth apertures 34 are  
15      formed in the diffusion chamber such that tissue may grow through such apertures 34, thereby firmly anchoring the diffusion chamber 20 in a substantially fixed position within the surgically-created pocket in which it is implanted.

- 20      Also in the embodiment of Figures 1-3, an optional suture tab 38 having suture passing apertures 40 is affixed to the outer surface of the tube 12, at a spaced distance proximal to the distal end 16 of the tube 12 to further facilitate suturing of the tube 12 in a desired position within the body.

- 25      Also in the embodiment of Figures 1-3, an optional concave abutment flange 42 is formed on the outer surface of the tube 12 to facilitate and maintain proper positioning of the tube 12 when implanted within the body in the glaucoma-treatment application described in detail herebelow. It will be appreciated that, although the embodiment shown uses a concave abutment flange 42, such abutment flange 42 may be of numerous different configurations

to facilitate and maintain the desired positioning of the tube 12 in various other anatomical structures and locations of the body.

The particular details and sizing of this concave abutment flange 42 in connection with a particular application of the invention for the treatment of glaucoma is described in more detail herebelow, and shown in Figures 5. In many glaucoma treatment applications, it will be desirable for such concave abutment flange 42 to have a width W of approximately 3mm, a depth D of approximately 1mm, and a height H of approximately 1mm.

The pressure-openable aperture 30 may specifically comprise a slit aperture 30 as shown in the drawings. Such slit aperture 30 is formed in the wall of the proximal portion PP of the tube 12, to facilitate outflow of fluid from the lumen 14 of the tube 12 into the inner chamber 26 of diffusion chamber 20. This pressure-openable slit aperture 30 is biased to a closed configuration whereby the opposite sides of the slit aperture 30 are in sealing contact with one another to prevent fluid from flowing from the lumen 14 of the tube 12 into the inner cavity 26 of the diffusion chamber 20 so long as the fluid pressure within the lumen 14 of the tube 12 is below a predetermined maximum pressure  $P_{MAX}$ . However, the pressure-openable slit aperture 30 is configured and constructed so as to spread apart (i.e., open) when the fluid pressure within the lumen 14 of the tube 12 exceeds such predetermined maximum pressure  $P_{MAX}$ , thereby allowing fluid to flow from the lumen 14 of tube 12 into the inner cavity 26 of the diffusion chamber 20 until the fluid pressure within the lumen 14 of the tube 12 falls below a predetermined aperture closing pressure  $P_{CLS}$ , at which time the biasing of the pressure-openable slit aperture 30 will cause such slit aperture 30 to once again assume its closed configuration. The predetermined maximum pressure  $P_{MAX}$  and the predetermined aperture closing pressure  $P_{CLS}$  will be determined on the basis of the intended application of the device 10, to facilitate drainage of fluid from a body cavity wherein the open distal end 16 of the tube 12 is located, into the diffusion chamber 10 when such pressure exceeds the

predetermined maximum pressure  $P_{MAX}$ , but to prevent such fluid pressure within the body cavity from falling below the predetermined closing pressure  $P_{CLS}$  so as not to inadvertently drain too much of such fluid from the body cavity. In this manner, the amount of fluid left within the affected body cavity should be sufficient to perform the intended physiological functioning of the fluid (if any), but such fluid will be prevented by the device 10 from over-accumulating within the body cavity in a manner which creates excessive or non-physiological pressure within the body cavity.

The specific size, shape, orientation and formation of the pressure-openable slit aperture 30 may vary, depending upon the desired predetermined maximum pressure  $P_{MAX}$  and predetermined closing pressure  $P_{CLS}$ . In the particular embodiment shown, the predetermined maximum pressure  $P_{MAX}$  which will cause the pressure-openable slit aperture 30 to open is a function of the thickness  $T$  of the wall of the tube, the width or thickness of the tool utilized to make the pressure-openable slit aperture 30 in the wall of the tube 12, and the angle  $A$  of such slit aperture 30 relative to a radial line or ray  $R$  which is projectible at  $90^\circ$  to the longitudinal axis  $LA$  of the tube 12. When the tool or instrument utilized to make the pressure-openable slit aperture 30 is of minimal width so as not to create a slit which is incapable of assuming a fully closed configuration, the factors which will determine the predetermined maximum pressure  $P_{MAX}$  at which the pressure-openable slit aperture 30 will open are a) the wall thickness  $T$  of the tube 12, b) the angle  $A$  of the slit aperture 30 relative to the transverse axis (e.g., radius line  $R$ ) of the tube 12, c) the length  $L$  of the slit aperture 30, and d) the internal diameter  $ID$  of the tube. With respect to the angle  $A$  of the slit aperture 30 relative to the radial line or ray  $R$  of the tube, it is to be appreciated that in embodiments such as that shown in Figure 4 wherein the lumen 14 of the tube 12 is round, the slit aperture 30 will form angle  $A$  relative to a radius line  $R$  which is projected from the inner end of the slit aperture 30 to the centerpoint of the round lumen 14. However, various

alternative configurations may be employed wherein the lumen 14 of the tube is other than round, and in such alternative configurations the angle A of the slit aperture 30 will be defined relative to a transverse axis projected from the inner end of the slit aperture 30 to a centerpoint or center-of-flow point within the

5 lumen 14 of the tube 12. In either instance, the angle A of the slit aperture 30 relative to such radial line or ray R will determine the amount of tube material which the slit aperture 30 must penetrate through, thereby determining at least in part the amount of fluid pressure which will be required to spread apart the adjacent sides of the slit aperture 30 to cause opening of the slit aperture 30.

10 For example, with reference to the showing of Figure 4, if the slit aperture 30 were to extend straight through the wall of the tube 12, the angle A would be 180°, and the slit aperture 30 would pass through the minimum amount of tubular material determined by the wall thickness of the tube 12. However, as the angle A decreases from 180° to 90°, the amount of tubular material through

15 which the slit aperture 30 must pass will increase, thereby requiring greater pressure to part the opposite sides of the slit aperture 30 to accomplish opening thereof. Thus, it is in this manner that the angle A of the slit aperture 30 relative to the radial line or ray R of the tube 12 will function as one of the variables which are determinative of the predetermined maximum pressure  $P_{MAX}$  and/or

20 the predetermined closing pressure  $P_{CLS}$  of the slit aperture 30.

It will be appreciated that the tube 12 and diffusion chamber 20 may be formed of any material which is suitable for the particular application for which the device 10 is to be used. Examples of materials of which the tube 12 may be formed include, but are not necessarily limited to silicone, hydrogels, polyurethanes, polyesters, latex, natural rubbers, and, cellulosics. Examples of the materials of which the diffusion chamber may be formed include, but are not necessarily limited to, cellulose acetate, cellulosics, polyesters, polyfluorocarbons, hydrogels, polyolefins, a hydrogel made from at least one

25

hydrophilic monomer and at least one olefinic/polyolefinic cross-linker, and, other natural polymers.

ii. Application of the Invention for Glaucoma Treatment

a. *Implantation of the Device to Control Intraocular Pressure*

5 Figure 5 shows the device of Figure 1, implanted within the human eye for treatment of glaucoma. the anatomical structures shown in Figure 5 are labeled in accordance with the following:

	Anterior Angle .....	AA
	Anterior Chamber .....	AC
10	Ciliary Body .....	CB
	Conjunctiva .....	CON
	Cornea .....	COR
	Iris .....	IR
	Lens .....	L
15	Sclera .....	SC
	Sinus Venosus Sclerae .....	SVS
	Suspensory Ligaments .....	SL

In this application of the device the tube 12 will typically have an outer diameter of approximately 0.6mm, an inner diameter of approximately 0.3mm and a length of approximately 40-45mm. The concave abutment flange 42 will be positioned approximately 5mm from the distal end 16 of the tube 12, and will have a height H of approximately 1mm, a width W of approximately 3mm and a depth D of approximately 1mm.

The shape of the concave abutment flange 42 may be other than circular, and preferably may be oval shape in the manner depicted in the figures. Such oval configuration of the concave abutment flange 42 will facilitate the desired passage of the flange 42 in a collapsed configuration through the opening formed into the anterior chamber AC of the eye, and will thereafter permit the

fully deployed and uncollapsed flange 42 to properly seat or nest within the peripheral corner of the anterior chamber AC, in the manner shown in Figure 5.

As shown, the diffusion chamber 20 and proximal portion of the tube 12 are implanted in a cavity formed between the conjunctiva CON and sclera SC, 5 on the lateral aspect of the ocular bulb. The diffusion chamber 20 may be doubled over or folded to facilitate insertion through a relatively small incisions and may subsequently be opened or unfolded while in the surgically-created pocket of tissue formed between the conjunctiva CON and sclera SC. The distal end 16 of the tube is advanced through an opening formed in the sclera, inboard 10 of the sinus venosus sclerae SVS. The concave abutment flange 42 is passed through the surgically formed opening in the sclera and is retracted so as to be in firm abutment with the sclera and/or adjacent tissue, thereby maintaining the tube 12 in its desired longitudinal position with the appropriate length of tube 12 extending into the anterior chamber AC. Suture tab 38 is secured to the 15 adjacent tissue of the conjunctiva CON by way of sutures, thereby affixing the distal portion of the tube 12 in its desired position, and maintaining the concave abutment flange 42 in contact with the sclera and/or adjacent tissue as described hereabove.

If necessary or desirable, the diffusion chamber 20 of the device 10 may 20 be initially secured within its desired implantation position by passing sutures through the suture-receiving apertures 36, as shown. Following implantation, tissue will ingrow through tissue ingrowth apertures 34 to further facilitate anchoring and attachment of the diffusion chamber 20 to the surrounding tissue of the conjunctiva CON and sclera SC. Thus, with the device 10 implanted 25 within the eye in the manner shown in Figure 5, excess aqueous humor in the anterior chamber AC will enter the open distal end 16 of the tube 12, and will flow through the lumen 14 of the tube 12. When the pressure of aqueous humor within the lumen 14 of the tube 12 exceeds the predetermined maximum pressure  $P_{MAX}$  the pressure-openable slit aperture 30 will be caused to open,

thereby allowing the access humor to flow out into the inner cavity 26 of the diffusion chamber 20. Such outflow of aqueous humor will continue until the pressure of aqueous humor within the lumen 14 of the tube 12 falls below the predetermined closing pressure  $P_{CLS}$  of the pressure-openable slit aperture 30,  
5 at which time the pressure-openable slit aperture 30 will once again assume its closed configuration. Thereafter, the pressure-openable slit 30 will remain closed until such time as the pressure of aqueous humor within the lumen 14 of the tube 12 once again exceeds the predetermined maximum pressure  $P_{MAX}$ .

For many glaucoma patients, the desired predetermined maximum  
10 pressure  $P_{MAX}$  will be approximately 15 mm/Hg, and the desired closing pressure  $P_{CLS}$  of the pressure-openable slit aperture 30 will be approximately 5mm/Hg. As explained hereabove, the length and angular orientation of the pressure-openable slit apertures 30 will be adjusted to provide these desired predetermined maximum pressure  $P_{MAX}$  and predetermined closing pressure  
15  $P_{CLS}$ . In this regard, the pressure of aqueous humor within the anterior chamber AC of the eye will be prevented from exceeding the predetermined maximum pressure  $P_{MAX}$  of approximately 15mm/Hg, and will also be prevented from falling below the predetermined closing pressure  $P_{CLS}$  of approximately 5mm/Hg. Thus, in this application of the present invention, the device 10 will operate to maintain  
20 pressure of aqueous humor within the anterior chamber within the 5-20mm/Hg range, and preferably in a range of approximately 5-15mm/Hg.

Excess aqueous humor which has passed through the tube 12 and into the inner cavity 26 of the diffusion chamber 20 will subsequently diffuse outwardly through the membrane walls 22a, 22b of the chamber and into the  
25 surrounding tissue. Such fluid will, thereafter, be assimilated by normal physiological action of the tissues.

In this glaucoma-treatment application, it is preferable that the membrane walls 22a, 22b of the diffusion chamber 20 be formed of cellulose acetate and/or polyvinylidene fluoride (PVDF), as such materials exhibit desirable host tissue

compatibility. This preferred membrane material will allow the aqueous humor which collects in the inner cavity 26 to diffuse outwardly therethrough, but will prevent cellular ingrowth, proteins or particulate matter from passing inwardly into the inner cavity 26 of the diffusion chamber 20 where such matter could a) 5 block or interfere with the pressure-openable slit apertures 30 or b) migrate through the lumen 14 of the tube 12 into the anterior chamber AC of the eye.

Also, in this glaucoma-treatment application, it is preferable that the tube 12 be formed of silicone.

***B. Sutureless Implantable Device for Controlling Intraocular Pressure***

Figures 8-13 are directed to a sutureless embodiment 10s of the implantable fluid shunting device 10 described above. With specific reference to Figures 8-11, there is shown a sutureless implantable fluid shunting device 10s which comprises an elongate tube 12s having a lumen 14s extending longitudinally therethrough and a diffusion chamber 20s mounted on the proximal end thereof. The tube 12s has an open distal end 16s, a closed proximal end 18s and a pressure openable aperture 30s located in a proximal portion PP of the tube 12s which extends into the interior of the diffusion chamber 20s.

The diffusion chamber 20s is constructed of an upper membrane wall 22sa and lower membrane wall 22sb. The upper and lower membrane walls 22sa, 22sb are sealed or connected to one another at their edges to form a sealed perimeter 24s. As shown, the tube 12s extends through a tube passage aperture 23s formed in the lower membrane wall 22sb of the diffusion chamber 20s, at an angle, such that an anterior portion of the diffusion chamber 20s overhangs the portion of the tube 12s which extends outside of the diffusion chamber's lower wall 22sb. As in the above-described suture-anchorable embodiment, the tube 12s of this device 10s is disposed such that the proximal portion PP of the tube 12s (i.e., the portion adjacent its proximal end 18s) extends into the inner cavity 26s of the diffusion chamber 20s. The portion of

the lower membrane wall 22sb which surrounds the tube passage aperture 23s is sealed to the outer wall of the tube 12s. As a result, any fluid which flows through the tube 12s and into the inner cavity 26s of the diffusion chamber 20s will not freely leak therefrom.

5        The diffusion chamber 20s is preferably formed of membranous material (e.g., permeable or semipermeable membrane material) which will permit the fluid which is desired to be drained by the tube 12s to flow from the inner cavity 26s of the diffusion chamber 20s, outwardly and into the region of the body wherein the diffusion chamber 20s is positioned, while preventing predetermined types of unwanted matter (e.g., proteins, solid particles which are greater than a predetermined size, etc.) from passing inwardly through such membrane and into the inner cavity 26s of the diffusion chamber 20s. Additionally, the material of the diffusion chamber 20s will prevent host cellular matter (e.g., tissues or cells such as fibroblasts, endothelium, epithelium, blood cells) from invading 10      (e.g., ingrowing or migrating) the outer surface or inner lumen of the tube 12s and/or the inner cavity 26s of the diffusion chamber 20s.

15      The pressure-openable aperture 30s may comprise a pressure-openable slit aperture, as shown in Figure 9. Such slit aperture 30s may be sized, configured, formed, located and operated in the same manner as the slit aperture 30 of the suture-anchorable device 10 shown in Figures 1-3 and described hereabove.

20      As illustrated in Figure 10, the diffusion chamber 20s of this device 10s is specifically sized and shaped such that it may be positioned within a subconjunctival pocket which has been surgically formed in one superior quadrant of the eye, between the locations at which two (2) adjacent rectus muscles RM attach to the ocular bulb OB (e.g., between the attachment point AP of the lateral rectus muscle and the attachment point AP of the superior or inferior rectus muscle). The width W, of that portion of the diffusion chamber 25      20s which resides posterior to the attachment points AP of the adjacent rectus

muscles RM between which the device 10s is implanted, is wider than the distance D between those muscle attachment points AP. Preferably, the width W<sub>3</sub> of that portion of the diffusion chamber 20s which resides anterior to those attachment points AP of the adjacent rectus muscles RM is also wider than the distance D between those muscle attachment points AP. The portion (i.e., the "inter-muscular" portion) of the diffusion chamber 20s which resides between the attachment points AP of the adjacent rectus muscles RM has a width W<sub>2</sub> which is at least slightly narrower than the distance D between those muscle attachment points AP. As a result, when the device 10s is implanted in the position shown in Figure 10, it will be prevented from migrating in either lateral direction LD1, LD2 by the abutment of the lateral sides of the diffusion chamber 20s against the attachment points AP of the rectus muscles RM. Additionally, the device 10s will be prevented from migrating in either the anterior direction AD or posterior direction PD by the abutment of the edges of the posterior portion (i.e., the portion of width W<sub>1</sub>) and anterior portion (i.e., the portion of width W<sub>3</sub>) of the diffusion chamber against the attachment points AP of the adjacent rectus muscles. Also, the device 10s is deterred from migrating in any direction by the engagement of the tube 12s, which extends downwardly through the lower wall 22sb of the diffusion chamber 20s, with the walls of the puncture tract through which the tube extends from the subconjunctival pocket in which it is positioned, into the anterior chamber AC of the eye. Still further, the device 10s is prevented from migrating in the posterior direction PD by the bottoming out of the posterior portion of the diffusion chamber 20s against the posterior end of the surgically-formed subconjunctival pocket and/or the abutment of the anterior portion (i.e. the portion of width W<sub>3</sub>) against the attachment points AP of the rectus muscles RM in instances where the width W<sub>3</sub> of that anterior portion AP of the diffusion chamber 20s is wider than the distance D between the muscle attachment points AP. In many applications, it may not be necessary for the anterior portion AP of the diffusion chamber 20s

to be of a width  $W_3$  which is wider than the distance D between the rectus muscle attachment points AP, as the potential for posterior migration of the device 10s may be adequately limited by a) the bottoming out of the posterior end of the diffusion chamber 20s against the posterior extent of the 5 subconjunctival pocket and/or b) the lateral abutment of the tube 12s against the walls of the puncture tract through which that tube 12s extends into the anterior chamber AC. However, in cases where the subconjunctival pocket is deeper than necessary, or where it is otherwise deemed desirable to further restrict the posterior migration of the device 10s, the surgeon may select a device 10s 10 which has an anterior portion of a width  $W_3$  that is wider than the distance D between the rectus muscle attachment points AP, thereby providing for further prevention of undesirable migration in the posterior direction PD.

It will be appreciated that the exact shape and dimensions of the diffusion chamber 20s may vary, while still incorporating the above-described 15 configurational attributes which allow it to engage and be held in place by, the adjacent rectus muscle attachment points AP. For example, Figure 12 shows a diffusion chamber 20s' which, while still within the scope of the present invention, has a shape which is different from that shown in Figures 8-11.

It will be further appreciated that this sutureless embodiment of the device 20 10s may be devoid on any suture passage apertures or suture tabs, as no sutures are required to be placed in the device 10s to hold it in place following implantation.

### ***C. A Preferred Technique for Implantation of the Sutureless Device in the Eye to Control Intraocular Pressure***

Figure 13 is a flow diagram showing the steps of a preferred technique for 25 implanting the sutureless fluid shunting device 10s within the eye in the manner illustrated in Figure 10.

Step 1: Formation of Conjunctival Incision and Subconjunctival Pocket:

A curved or straight incision IN of approximately 5 millimeters length is formed through the conjunctival layer, at the limbus. Thereafter, standard ophthalmological surgical technique is used to separate the conjunctival tissue from the underlying scleral tissue, thereby creating a subconjunctival pocket in a superior quadrant of the eye, posterior to the incision IN and between adjacent rectus muscles (e.g., between the superior rectus muscle RM and the lateral rectus muscle RM).

Step 2: Insertion of the Implantable Fluid Shunting Device:

- 10 With the diffusion chamber 20s of the device 10s in a collapsed (e.g., folded, rolled or compressed) state, the diffusion chamber 20s is inserted, posterior end first, through the incision IN and into the subconjunctival pocket. Thereafter, open (e.g., unfold, unroll or decompress) the diffusion chamber so that a) the inter-muscular portion of the diffusion chamber 20s of width  $W_2$ ,  
15 resides between the attachment points AP of the adjacent rectus muscles RM, and b) the posterior portion of the diffusion chamber 20s of width W, resides posterior to the attachment points AP of rectus muscles RM.

Step 3: Creation of Trans-Trabecular Puncture Tract:

- 20 A needle or other puncturing member (e.g., a 23 gage needle) is then inserted through the incision IN and advanced, on a path which is substantially parallel to the iris, to create a puncture tract which extends from a location on the anterior scleral surface (i.e., the floor of the surgically formed subconjunctival pocket) approximately 1.5 millimeters proximal to the limbus into the anterior chamber AC. If necessary, a quantity of viscoelastic substance (e.g., hyaluronic acid or methyl cellulose) or other temporary embolization material may be deposited in the freshly-formed puncture tract to prevent backflow of aqueous humor from the anterior chamber and the possibility of resultant hypotony, while  
25 the tube 12s is being prepared for insertion through the puncture tract.

**Step 4: Insertion of Tube Into Anterior Chamber:**

The tube 12s is then inserted, distal end first, through the puncture tract until the distal end 16s of the tube enters the anterior chamber AC but does not touch the iris IR or corneal epithelium. The surgeon may trim the tube to length  
5 prior to insertion, to ensure that the distal end 16s of the tube 12s will reside at its desired position within the anterior chamber AC.

**Step 5: Closure of Conjunctival Incision:**

The small conjunctival incision IN is then closed by way of an absorbable suture or other suitable closure means (e.g., a polymer film which may be applied to the surface of the conjunctiva to hold the incision IN closed until healed).  
10

By the above-described five--step procedure, the implantable fluid shunting device 10s of the present invention may be surgically implanted in the eye, without the use of sutures (i.e., stitches, staples, clips, etc) to hold or  
15 anchor the device 10s at its desired position within the eye, relying instead on the engagement and interaction of the walls and/or edges of the diffusion chamber 20s and/ot tube 12s with the surrounding tissues, to hold the device 10s in its desired implantation position.  
20

**iii. Application of the Invention for Treatment of Hydrocephalus**

Figure 6 shows a variant of the device shown in Figures 1-3, implanted in the human body for treatment of hydrocephalus.  
25

In this application of the device 10, the device 10 is devoid of the optional concave abutment flange 42. The device 10 is implanted such that the diffusion chamber 20 is positioned within the peritoneum, and the tube 12 is passed subcutaneously over the thorax, neck and into the base of the skull. The distal portion of the tube 12 may reside in the space between the brain and cranium, or may be inserted into a ventricle of the vein in accordance with the applicable treatment technique for the particular case of hydrocephalus being treated. The optional suture tab 38 may be employed to anchor the tube 12 in its desired

position within the cranial vault. Also, the suture passage apertures 34, 36 formed on the diffusion chamber 20 may be utilized to suture the diffusion chamber 20 in its desired position within the patients abdomen.

When the device 10 has been implanted in the manner shown in Figure 5 6, excess cerebrospinal fluid will enter the open distal end 16 of the tube 12 and will flow through the lumen 14 of the tube. When the cerebrospinal fluid pressure within the lumen 14 of the tube 12 exceeds the predetermined maximum pressure  $P_{MAX}$ , the pressure-openable slits 30 will open, thereby allowing the excess cerebrospinal fluid flow into the inner cavity 26 of the 10 diffusion chamber 20.. Such outflow of cerebrospinal fluid will continue until the pressure of cerebrospinal fluid within the lumen 14 of the tube 12 falls below the predetermined closing pressure  $P_{CLS}$ .

In many hydrocephalus patients, the desired predetermined maximum pressure  $P_{MAX}$ , for treatment of hydrocephalus will be in the range of 10-15 20mm/Hg, and the desired predetermined closing pressure  $P_{CLS}$  will be in the range of 0-10mm/Hg. In this manner, the pressure of cerebrospinal fluid within the ventricle of the brain, or otherwise within the cranium, may be maintained in a prescribed range, such as a preferred range of 5-14mm/Hg, in accordance with the particular predetermined  $P_{MAX}$  and  $P_{CLS}$  of the device 10.

#### 20 iv. Alternative Configurations/Applications of the Invention

Figures 7a-7g show alternative embodiments of the device 10a-10g wherein the diffusion chamber 20a-20g is of varying configuration, to facilitate use of the device 10-10g in various other applications.

It will be appreciated that, the diffusive surface area of the diffusion 25 chamber 20a-20g may be altered by changing the shape of the diffusion chamber 20-20g. Moreover, alterations or variations in the shape of the diffusion chamber 20-20g, especially those wherein openings or invaginations are formed in the diffusion chamber 20-20g, may form areas into which tissue may ingrow so as to soundly anchor and fix the diffusion chamber 20-20g within

its desired implantation position. The utilization of indigenous tissue ingrowth as a means for physical fixation and anchoring of the diffusion chamber 20-20g is desirable in that it may eliminate the need for the use of permanent sutures for anchoring of the diffusion chamber 20-20g, as sutures may tend to exert physical stress or force upon the diffusion chamber 20-20g and/or adjacent tissue. Furthermore, promoting tissue ingrowth within specific regions of the diffusion chamber 20-20g may firmly anchor and hold the diffusion chamber 20-20g in its desired implantation position so as to deter or prevent post-surgical micromovement of the device 10. In this regard, the embodiments illustrated in Figures 7a-7g incorporate various modifications wherein multiple projections, invaginations, and other configurational variations are formed in the diffusion chamber 20a-20g.

Additionally, it will be appreciated that the shape of the diffusion chamber may be modified to facilitate a) folding of the diffusion chamber to facilitate its insertion into a specific area of the body and b) ease of placement and retention of the diffusion chamber 20a-20g at its intended site of implantation.

The alternative embodiments shown in Figures 7a-7g are merely examples of the multitude of shapes and configurations in which the diffusion chamber 20a-20g may be formed and, accordingly, the intended shape or configuration of the diffusion chamber 20 shall not be limited to only those shapes and configurations shown in the drawings, but shall include any and all other shapes or configurations in which the diffusion chamber 20 may be formed.

In particular, the diffusion chambers 20a, 20e, 20g shown in Figures 7a, 25 7e, and 7g, respectively, have curved or tapered outer edges whereby the proximal end of the diffusion chambers 20a, 20e, 20g is narrower than its distal end, thereby facilitating easy extraction and removal of the diffusion chamber 20a, 20e, 20g, if and when such removal is desired.

The invention has been described hereabove with reference to certain presently preferred embodiments, and no attempt has been made to describe all possible embodiments in which the invention may take physical form. Indeed, numerous modifications, additions, deletions and alterations may be  
5 made to the above-described embodiments without departing from the intended spirit and scope of the invention. Accordingly, it is intended that all such additions, deletions, modifications and alterations be included within the scope of the following claims.

WHAT IS CLAIMED IS:

1        1. A fluid shunting device which is implantable in the eye of a  
2 mammalian patient, within a subconjunctival pocket formed between two rectus  
3 muscles which are anatomically attached to the eye with a spaced distance  
4 therebetween, said device being operative to control the pressure of fluid within  
5 the anterior chamber of the eye without the use of sutures to hold the device in  
6 its desired implanted position, said device comprising:

7              a tube having a proximal end, a distal end, a side wall, and a  
8 lumen extending longitudinally therethrough;

9              a diffusion chamber having an inner cavity formed therewithin, a  
10 posterior portion of a width greater than the distance between said rectus  
11 muscles, and an inter-muscular portion of a width less than the distance  
12 between said rectus muscles;

13              said diffusion chamber being mounted on the proximal end of the  
14 tube such that fluid which enters the distal end of the tube may flow  
15 through the lumen of the tube and into the inner cavity of the diffusion  
16 chamber:

1        2. The device of Claim 1 wherein the distal end of the tube  
2 is insertable into the anterior chamber of the eye, and the diffusion chamber is  
3 positionable within the subconjunctival pocket, posterior to the limbus, such that  
4 its inter-muscular portion is between the locations at which said rectus muscles  
5 are anatomically attached to the eye, and its posterior portion is posterior to the  
6 locations at which said rectus muscles are anatomically attached to the eye.

1        3. The device of Claim 1 wherein the diffusion chamber further  
2 comprises:

1                   an anterior portion of a width greater than the distance between  
2    said rectus muscles, said device being further positionable within the  
3    subconjunctival pocket such that its anterior portion is anterior to the locations  
4    at which said rectus muscles are anatomically attached to the eye.

1         4.    The device of Claim 1 wherein a pressure-openable aperture is  
2    formed in said tube, said pressure-openable aperture being biased to a closed  
3    configuration, and being openable in response to fluid pressure exceeding a  
4    predetermined maximum pressure, within the lumen of said tube distal to said  
5    pressure openable aperture.

1         5.    The device of Claim 1 wherein said diffusion chamber  
2    comprises at least one membrane formed of material which will allow said fluid  
3    to diffuse out of the inner cavity of said diffusion chamber, while preventing  
4    predetermined types of matter from passing through said membrane into the  
5    inner cavity of said diffusion chamber.

1         6.    The device of Claim 5 wherein said membrane is a permeable  
2    membrane.

1         7.    The device of Claim 5 wherein said membrane is a semipermeable  
2    membrane.

1         8.    The device of Claim 5 wherein said predetermined types of matter  
2    which said membrane will prevent from passing into said diffusion chamber are  
3    selected from the group of matter types consisting of:

- 4                 a)    microbes;
- 5                 b)    proteins;
- 6                 c)    particles exceeding 5 microns in size; and,

7                   d)     host cellular matter.

1               9.     The device of Claim 5 wherein said diffusion chamber comprises  
2     material which will allow said fluid to diffuse out of the inner cavity of the  
3     diffusion chamber, but will prevent host cellular matter from entering the inner  
4     cavity of the diffusion chamber.

1               10.    The device of Claim 1 wherein said diffusion chamber is formed  
2     at least partially of materials selected from the group of materials consisting of:

3                   cellulose acetate;  
4                   cellulosics;  
5                   polyesters;  
6                   polyfluorocarbons;  
7                   polyvinylidene fluoride;  
8                   hydrogels;  
9                   polyolefins;  
10                  a hydrogel made from at least one hydrophilic monomer and at  
11                  least one olefinic/polyolefinic cross-linker; and,  
12                  other natural polymers.

1               11.    The device of Claim 1 wherein said tubing is formed at least  
2     partially from material selected from the group of materials consisting of:

3                   silicone;  
4                   hydrogels;  
5                   polyurethanes;  
6                   polyesters;  
7                   latex;  
8                   natural rubbers; and,  
9                   cellulosics.

10           12. The device of Claim 1 wherein said diffusion chamber comprises:  
11                   an upper membrane wall having at least one peripheral edge; and,  
12                   a lower membrane wall having at least one peripheral edge;  
13                   said upper and lower membrane walls being fused to one another  
14                   about their peripheral edges to form said diffusion chamber.

1           13. The device of Claim 4 wherein said pressure-openable aperture  
2                   comprises an elongate slit.

1           14. The device of Claim 13 wherein said elongate slit is formed in said  
2                   tube such that said elongate slit is substantially parallel to the longitudinal axis  
3                   of the tube.

1           15. The device of Claim 13 wherein said tube has a radius, and  
2                   wherein said elongate slit extends through the wall of said tube at an angle  
3                   relative to the radius of which has been predetermined to cause said slit to open  
4                   when a desired maximum pressure  $P_{MAX}$  of fluid is present within the lumen of  
5                   the tube.

1           16. The device of Claim 1 wherein the diffusion chamber has a  
2                   lower wall through which a tube passage aperture is formed, a proximal portion  
3                   of said tube being inserted through said tube passage aperture and into the  
4                   inner cavity of the diffusion chamber, the lower wall of said diffusion chamber  
5                   being sealed to the wall of said tube.

1           17. In a device which is implantable in the eye to treat a disorder of  
2                   the eye, the improvement comprising:  
3                        a first portion of the device having a width which is less than the distance  
4                        between attachment points of adjacent recti muscles, and at least a second

5 portion of the device having a width that is greater than the distance between  
6 attachment points of adjacent recti muscles, such that when the device is  
7 implanted in the eye first portion between the attachment points of adjacent recti  
8 muscles, the device will be prevented from moving in at least one direction by  
9 the abutment of at least the second portion of the device against the adjacent  
10 recti muscles.

1           18. A method for treating glaucoma in a mammalian eye which has a  
2 plurality of rectus muscles attached thereto at spaced-apart attachment  
3 locations, by implanting a fluid shunting device at an intended location within the  
4 eye to shunt excess fluid from the anterior chamber of the eye, said fluid  
5 shunting device being implanted by a method which comprises the steps of:

- 6           a. forming a subconjunctival pocket in the eye, between the  
7 attachment locations of adjacent recti muscles;
- 8           b. positioning said fluid shunting device in the intended implantation  
9 location between the attachment locations of adjacent recti  
10 muscles, without suturing the device to the eye; and,
- 11          c. closing the subconjunctival pocket, such that the device will  
12 thereafter be prevented from moving from said intended location  
13 by abutment of the device against the adjacent rectus muscles.

1           19. The method of Claim 18 wherein the implantable fluid shunting  
2 device comprises a tube connected to a diffusion chamber, and wherein said  
3 diffusion chamber has an inter-muscular portion of a width less than the distance  
4 between the attachment locations of the adjacent recti muscles and a posterior  
5 portion of a width greater than the distance between the attachment locations  
6 of the adjacent recti muscles, and wherein step b of the method further  
7 comprises:

- 8           i. placing the inter-muscular portion of the diffusion chamber  
9           between the attachment locations of the adjacent recti muscles;  
10          ii. placing the posterior portion of the diffusion chamber posterior to  
11           the attachment locations of the adjacent recti muscles; and,  
12          iii. inserting the tube into the anterior chamber of the eye such that  
13           excess fluid will pass from the anterior chamber, through the tube,  
14           and into the diffusion chamber.

1           20. The method of Claim 18 wherein the implantable fluid shunting  
2 device comprises a tube connected to a diffusion chamber, and wherein said  
3 diffusion chamber has an inter-muscular portion of a width less than the distance  
4 between the attachment locations of the adjacent recti muscles, a posterior  
5 portion of a width greater than the distance between the attachment locations  
6 of the adjacent recti muscles and an anterior portion of a width greater than the  
7 distance between the attachment locations of the adjacent recti muscles, and  
8 wherein step b of the method further comprises:

- 9           i. placing the inter-muscular portion of the diffusion chamber  
10           between the attachment locations of the adjacent recti muscles;  
11          ii. placing the posterior portion of the diffusion chamber posterior to  
12           the attachment locations of the adjacent recti muscles;  
13          iii. placing the anterior portion of the diffusion chamber anterior to the  
14           attachment locations of the adjacent recti muscles; and,  
15          iv. inserting the tube into the anterior chamber of the eye such that  
16           excess fluid will pass from the anterior chamber, through the tube,  
17           and into the diffusion chamber.

1           21. The method of Claim 18 wherein the implantable fluid shunting  
2 device comprises a tube connected to a diffusion chamber, and wherein step b  
3 comprises:

- 4           i. passing a needle parallel to the iris, from the scleral surface within  
5 the subconjunctival pocket into the anterior chamber, thereby forming a  
6 penetration tract from the subconjunctival pocket to the anterior chamber;
- 7           ii. placing the diffusion chamber of the device in a collapsed  
8 configuration and inserting it into the subconjunctival pocket;
- 9           iii. deploying the diffusion chamber of the device to an uncollapsed  
10 configuration such that a portion of the diffusion chamber is located between the  
11 adjacent recti muscles; and,
- 12          iv. inserting the tube of the device through the penetration tract and  
13 into the anterior chamber.

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## Abstract

Sutureless, implantable fluid shunting devices and associated methods for controlling the pressure of fluids within anatomical spaces or cavities of the body. The device generally comprises a tube having a diffusion barrier (e.g., diffusion chamber) formed on a proximal end thereof. Fluid which flows through the tube will collect within the diffusion chamber and will diffuse outwardly therethrough. However, the presence of the diffusion chamber will prevent microbes, cells or other matter from interfering with or backflowing through the tube. Additionally, the tube may be provided with a pressure-openable aperture through which fluid from the tube may flow into the diffusion chamber. Such pressure-openable aperture will remain closed, until the pressure of fluid within the tube exceeds a predetermined maximum pressure  $P_{MAX}$ . In this manner, the pressure-openable aperture will limit the amount of fluid drained from the anatomical space or cavity of the body, thereby avoiding hypotony within such anatomical space or cavity. The diffusion barrier of the device is preferably configured to fit between, and to be engaged by, adjacent recti muscles of the eye. Such engagement of the diffusion barrier with the adjacent recti muscles serves to prevent unwanted migration or post-implantation movement of the device, without the need for suturing of the device to the tissue of the eye.

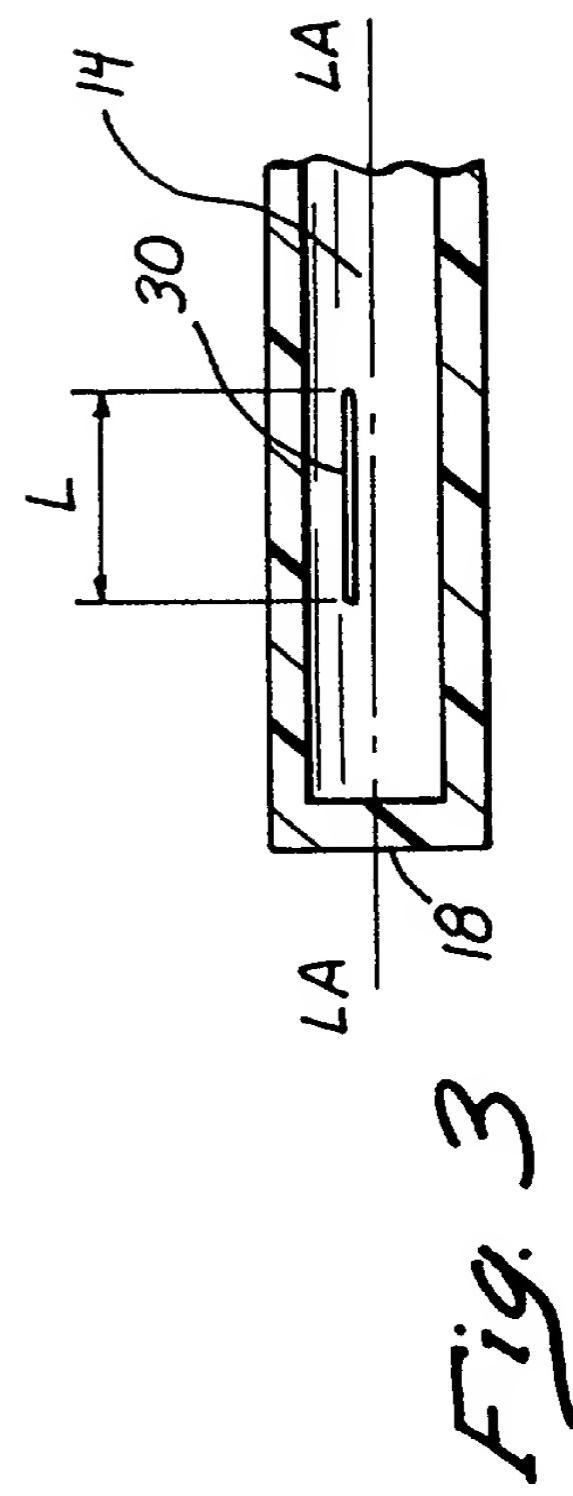
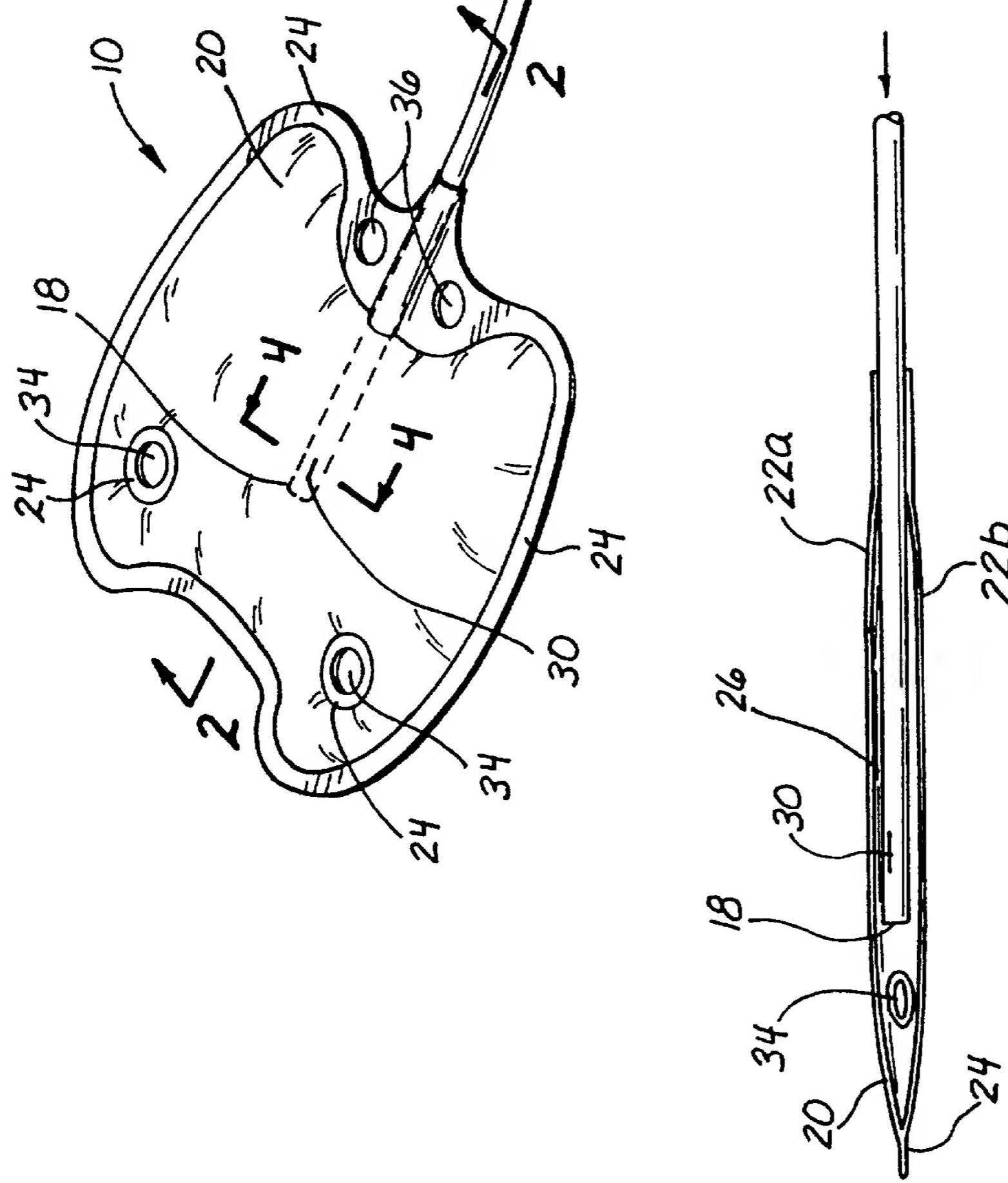
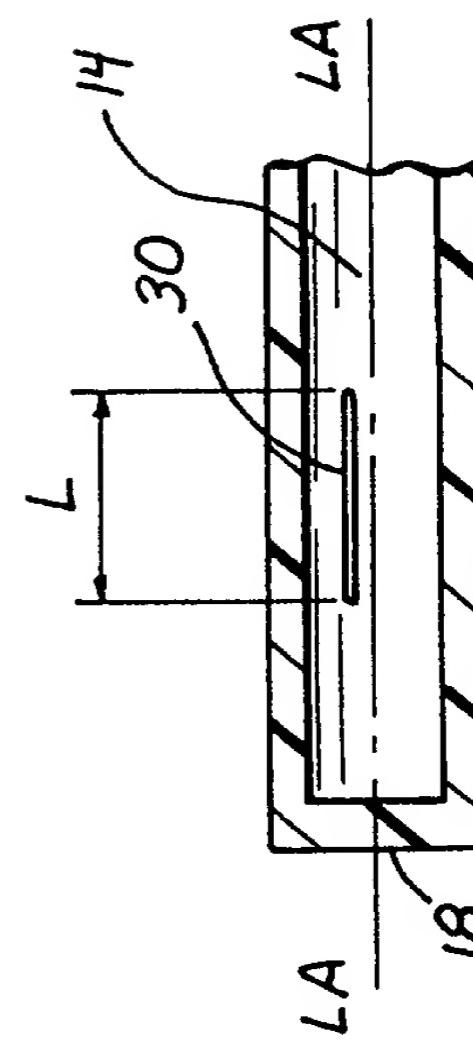


Fig. 3



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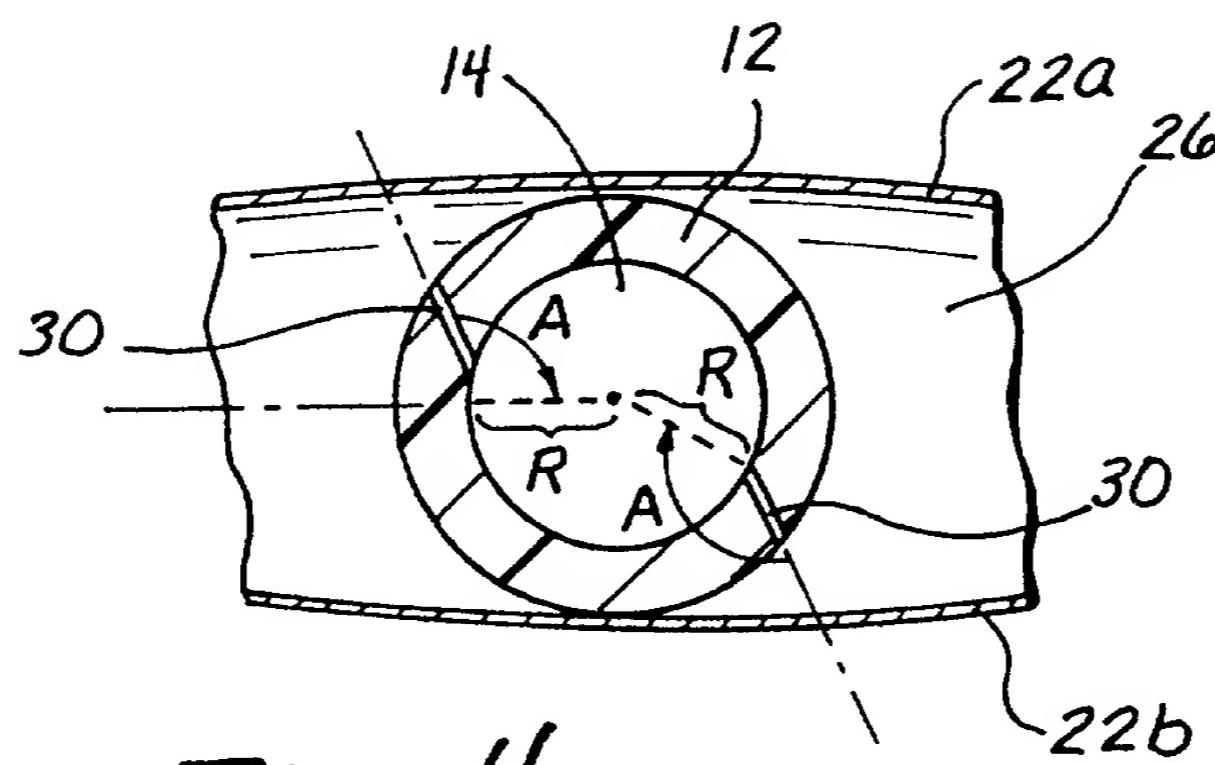


Fig. 4

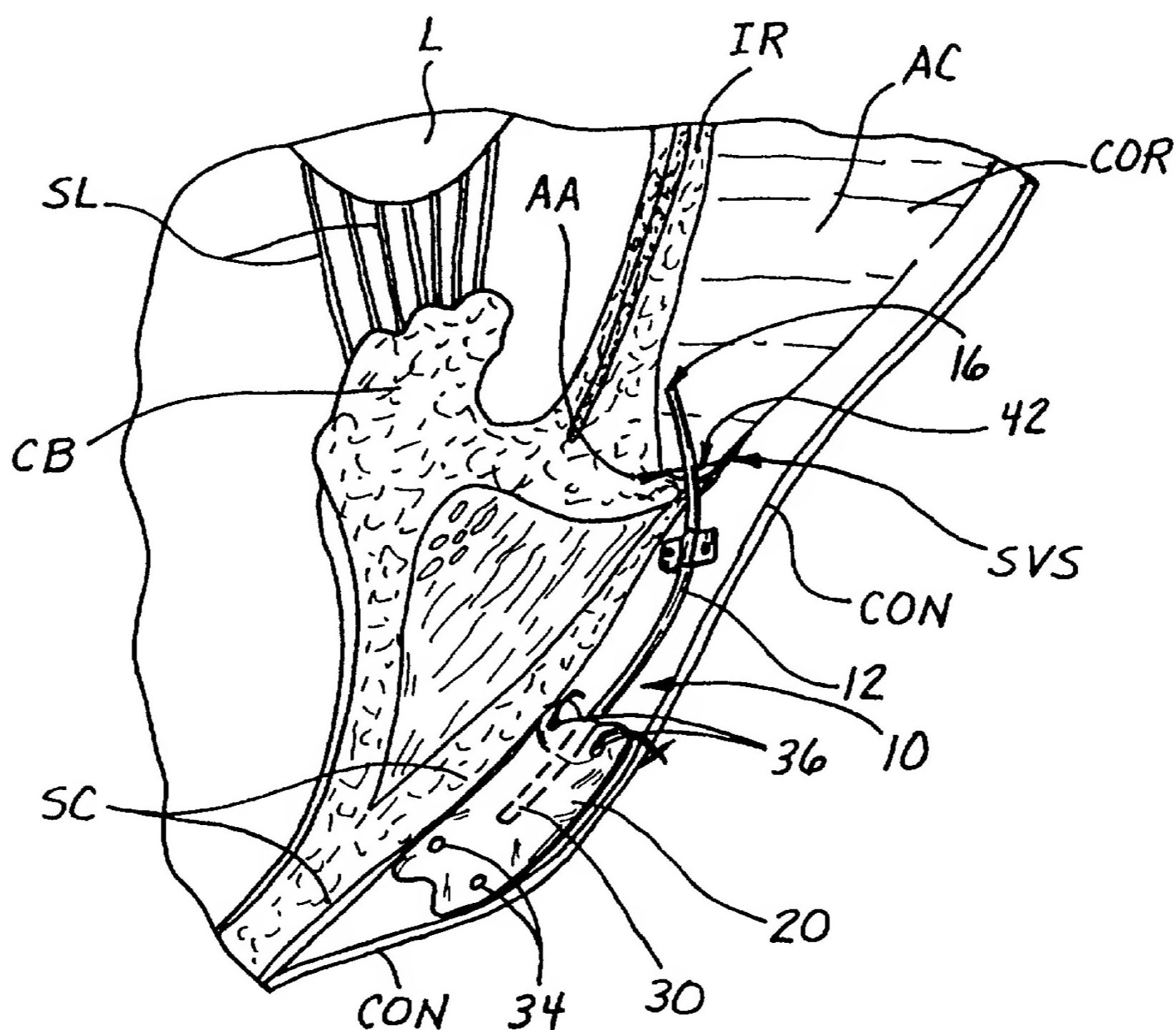
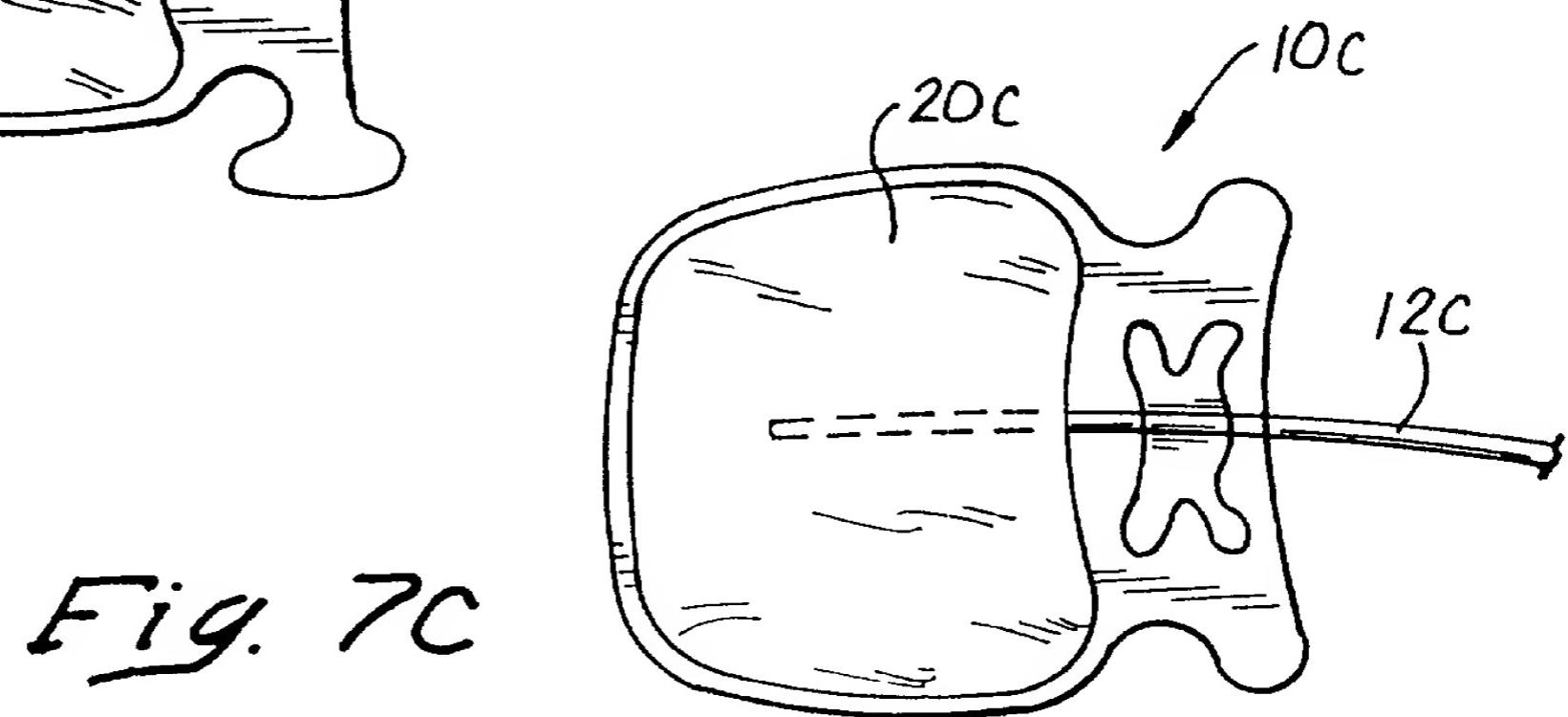
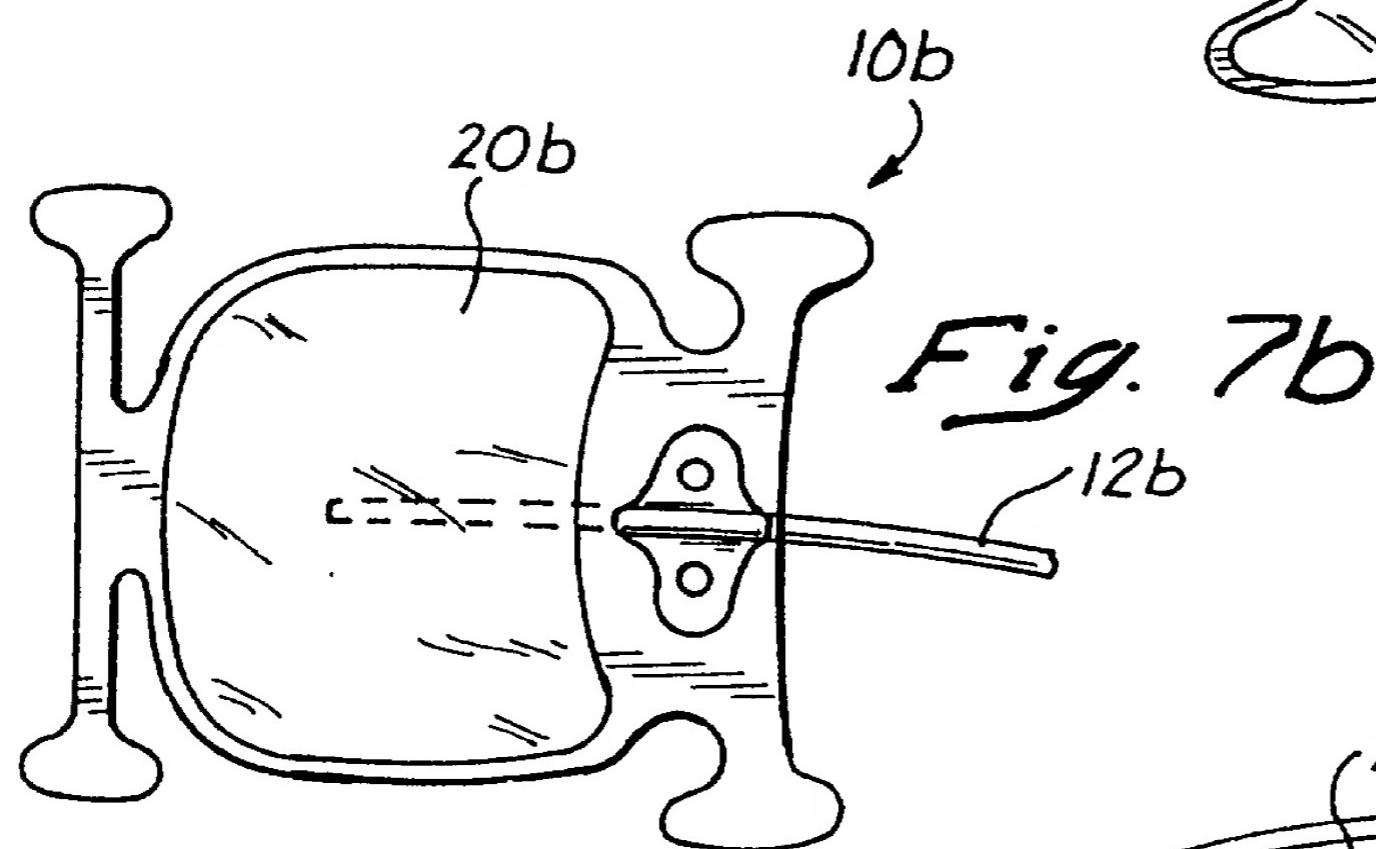
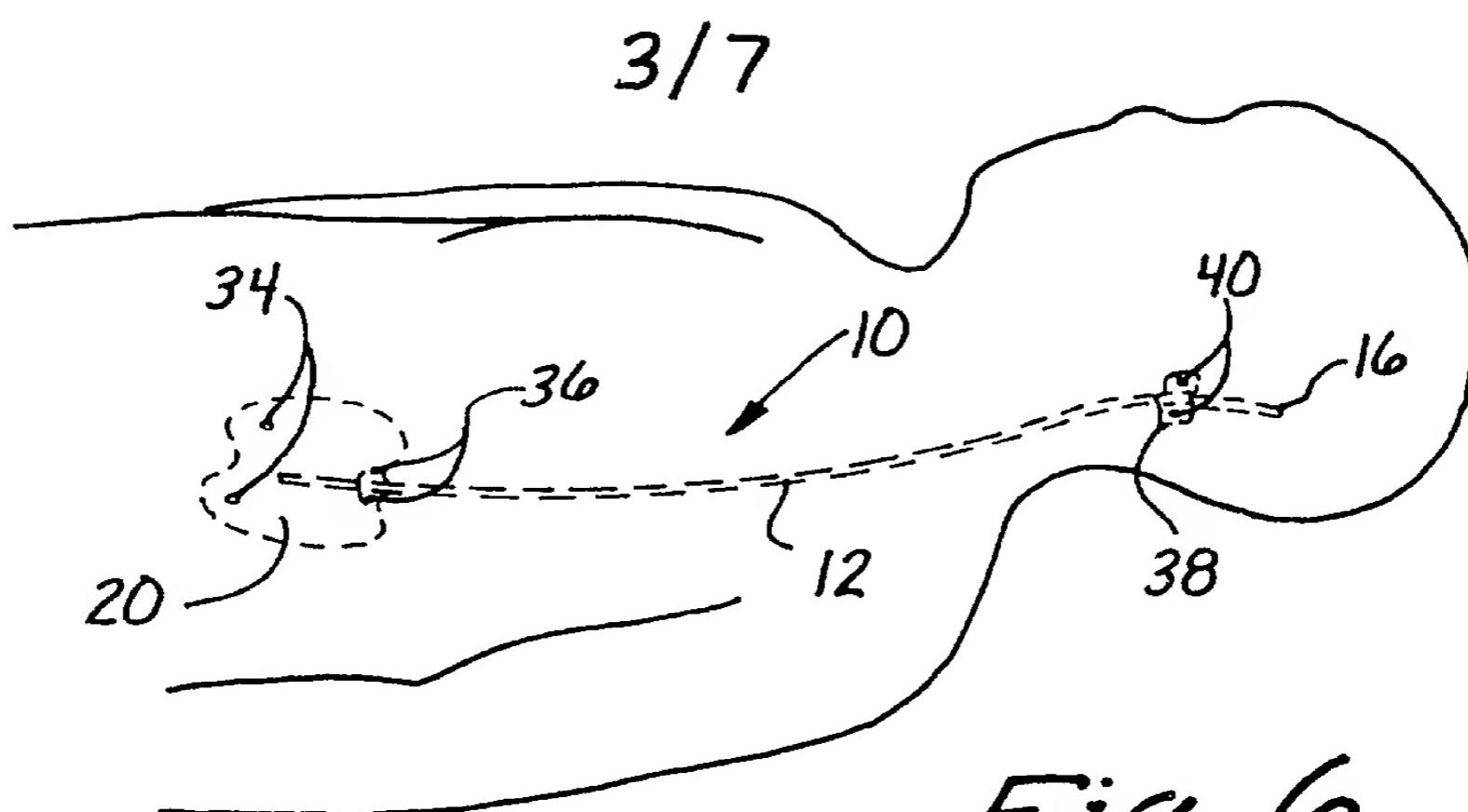


Fig. 5



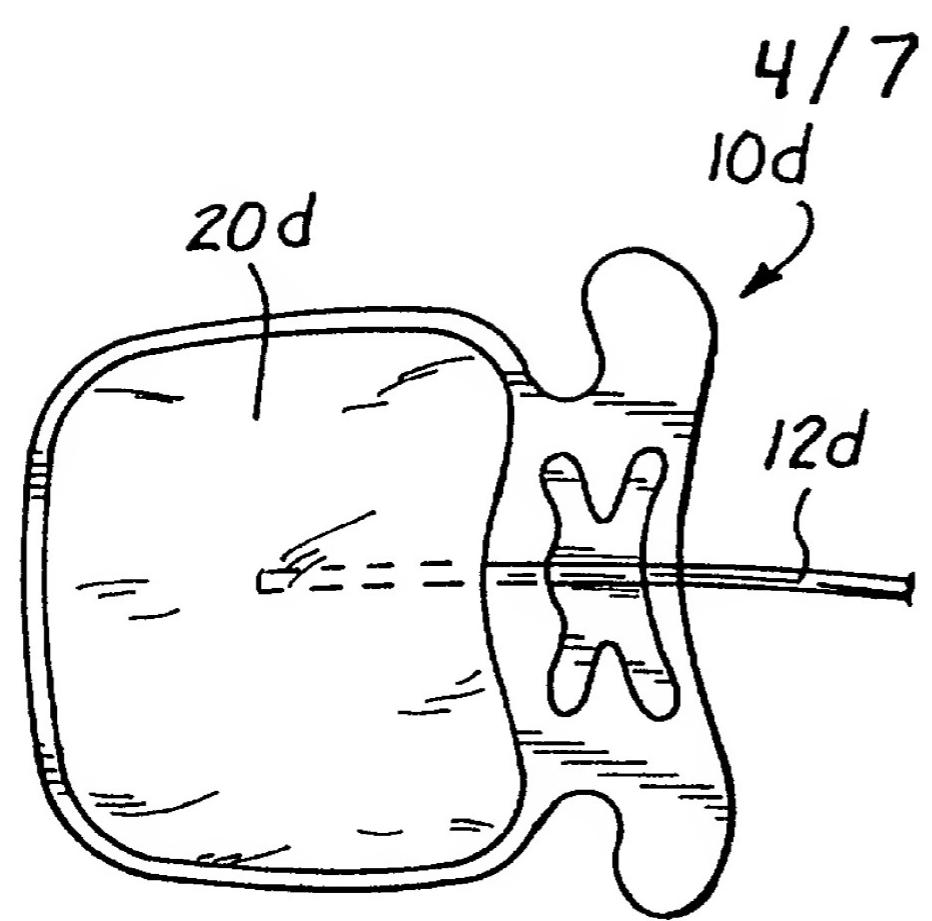


Fig. 7d

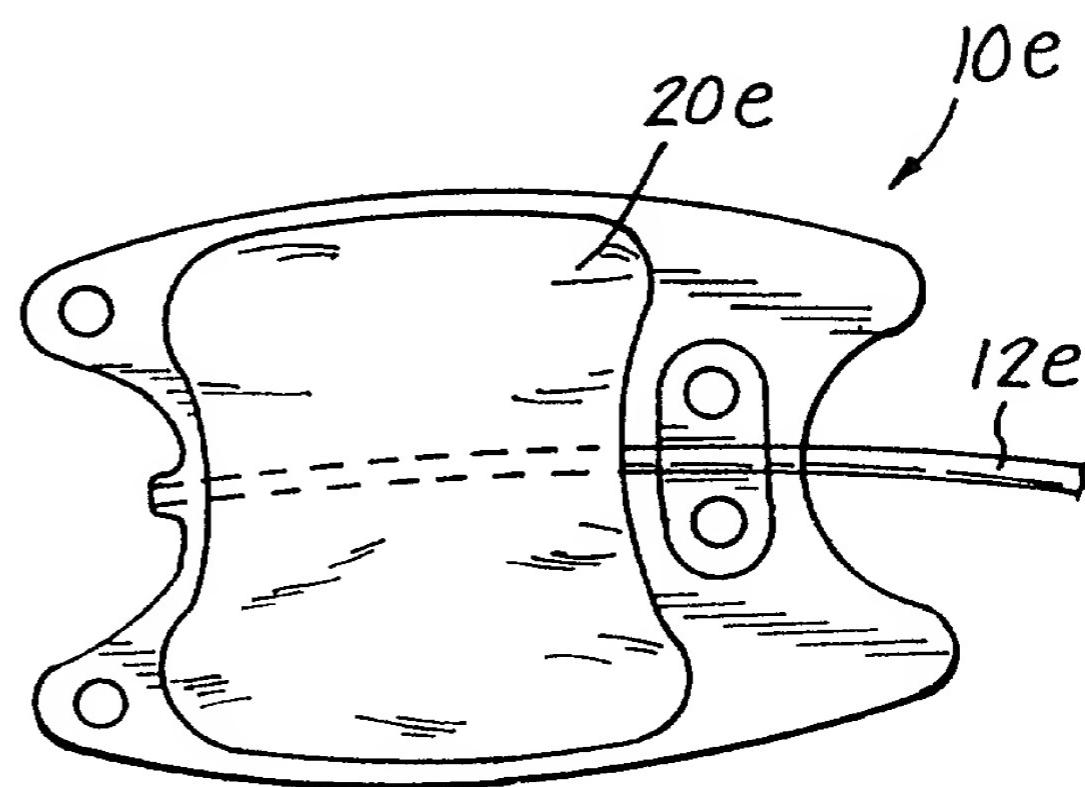


Fig. 7e

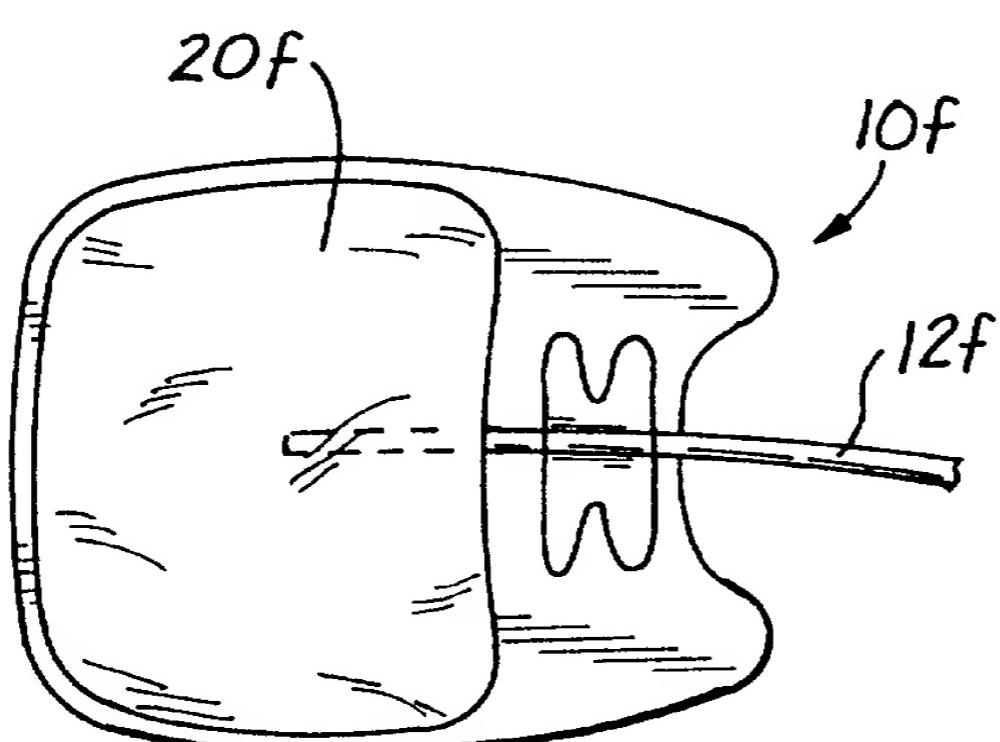


Fig. 7f

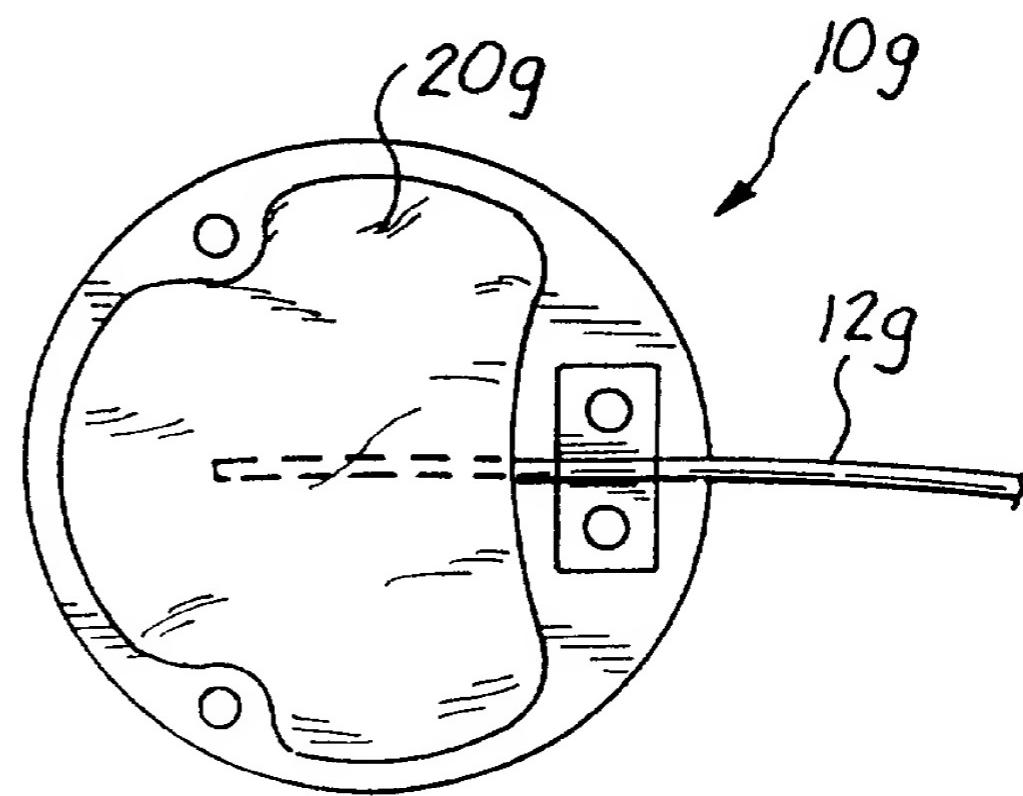


Fig. 7g

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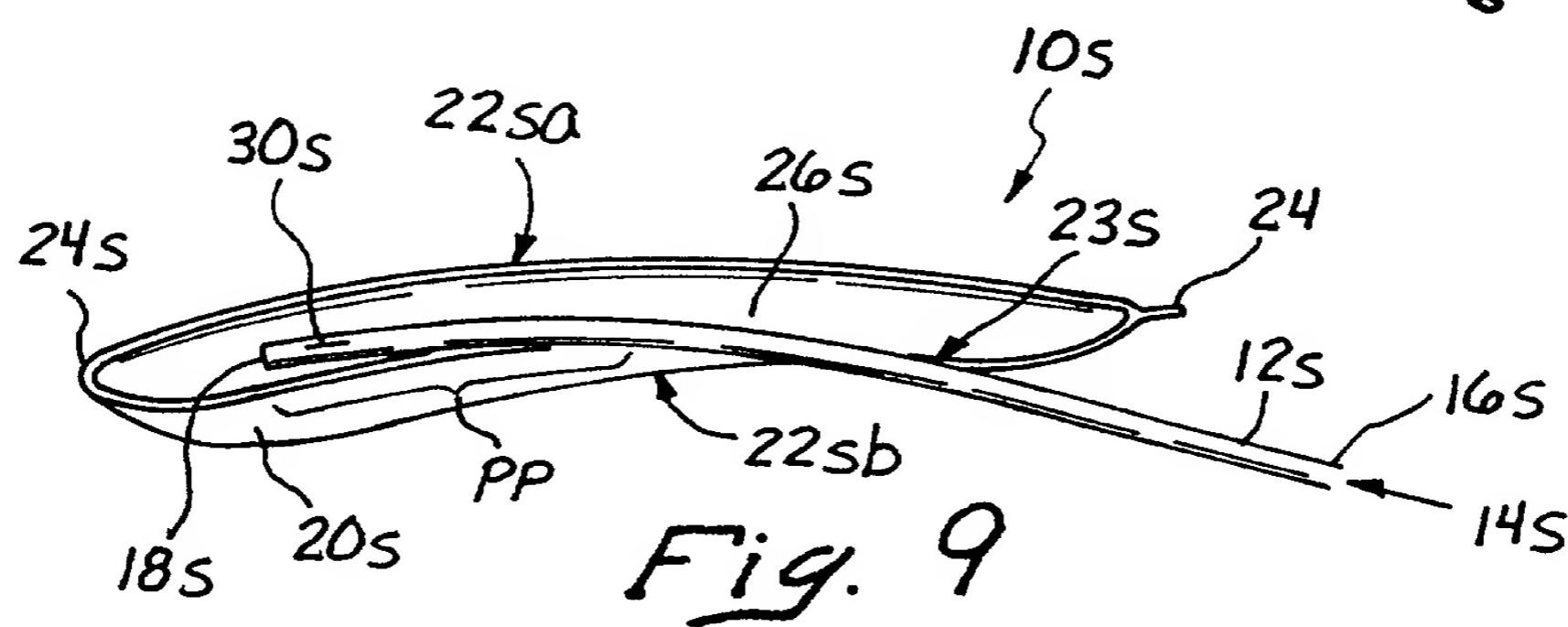
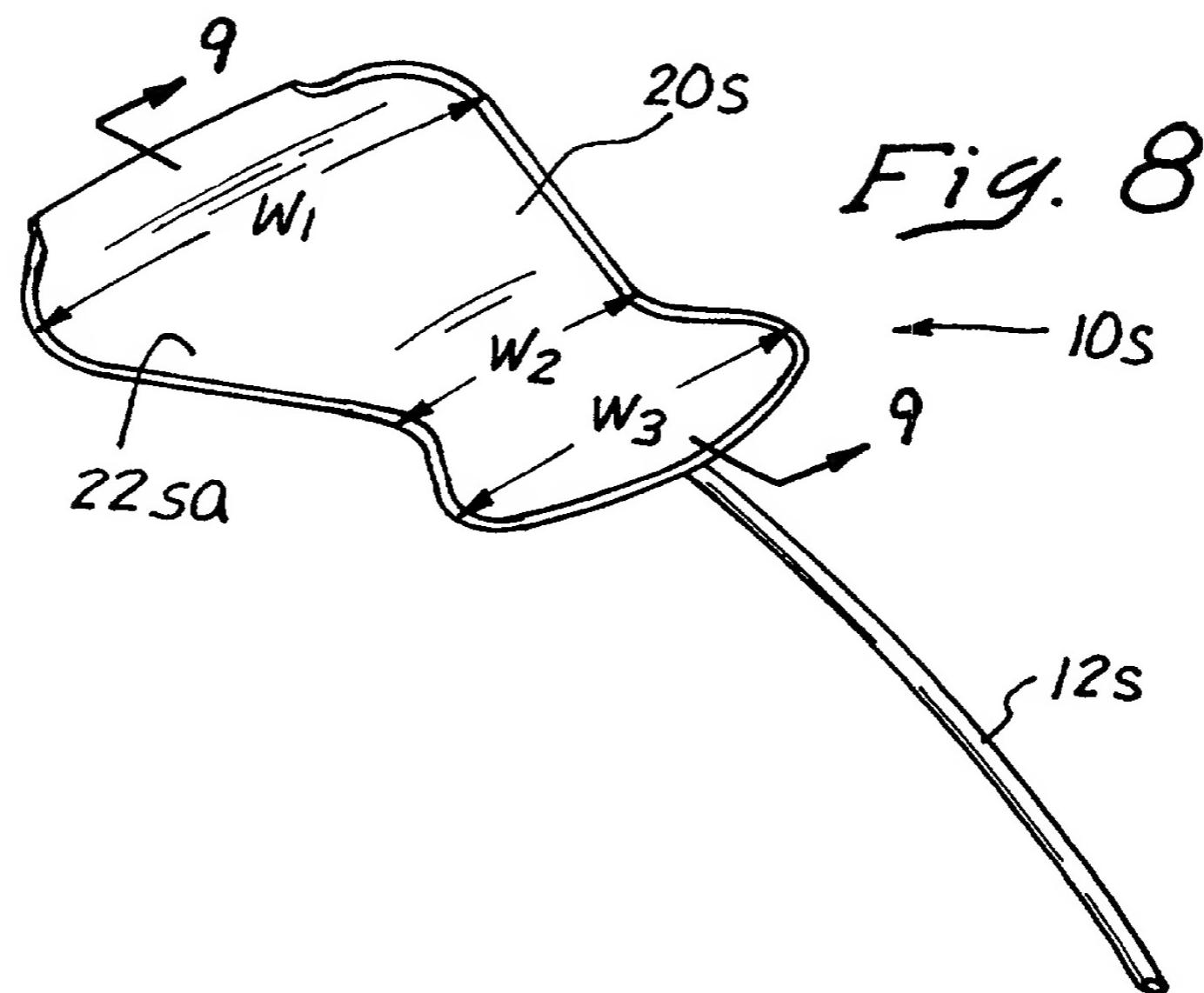
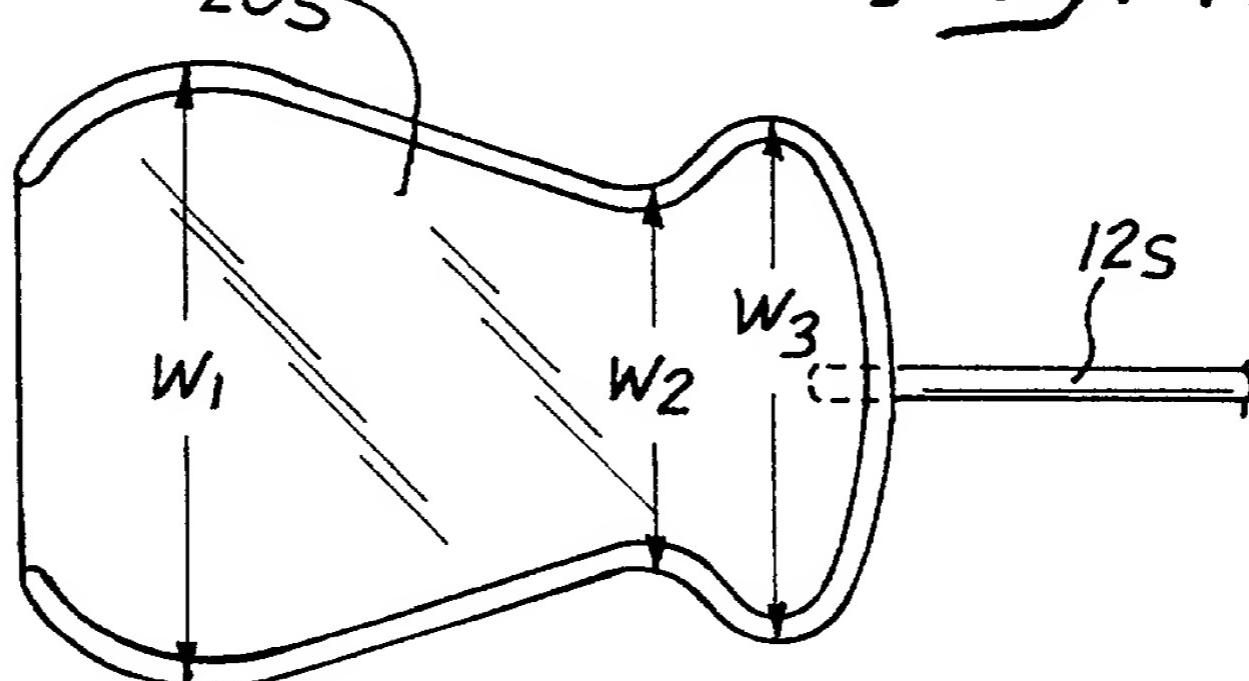


Fig. 11



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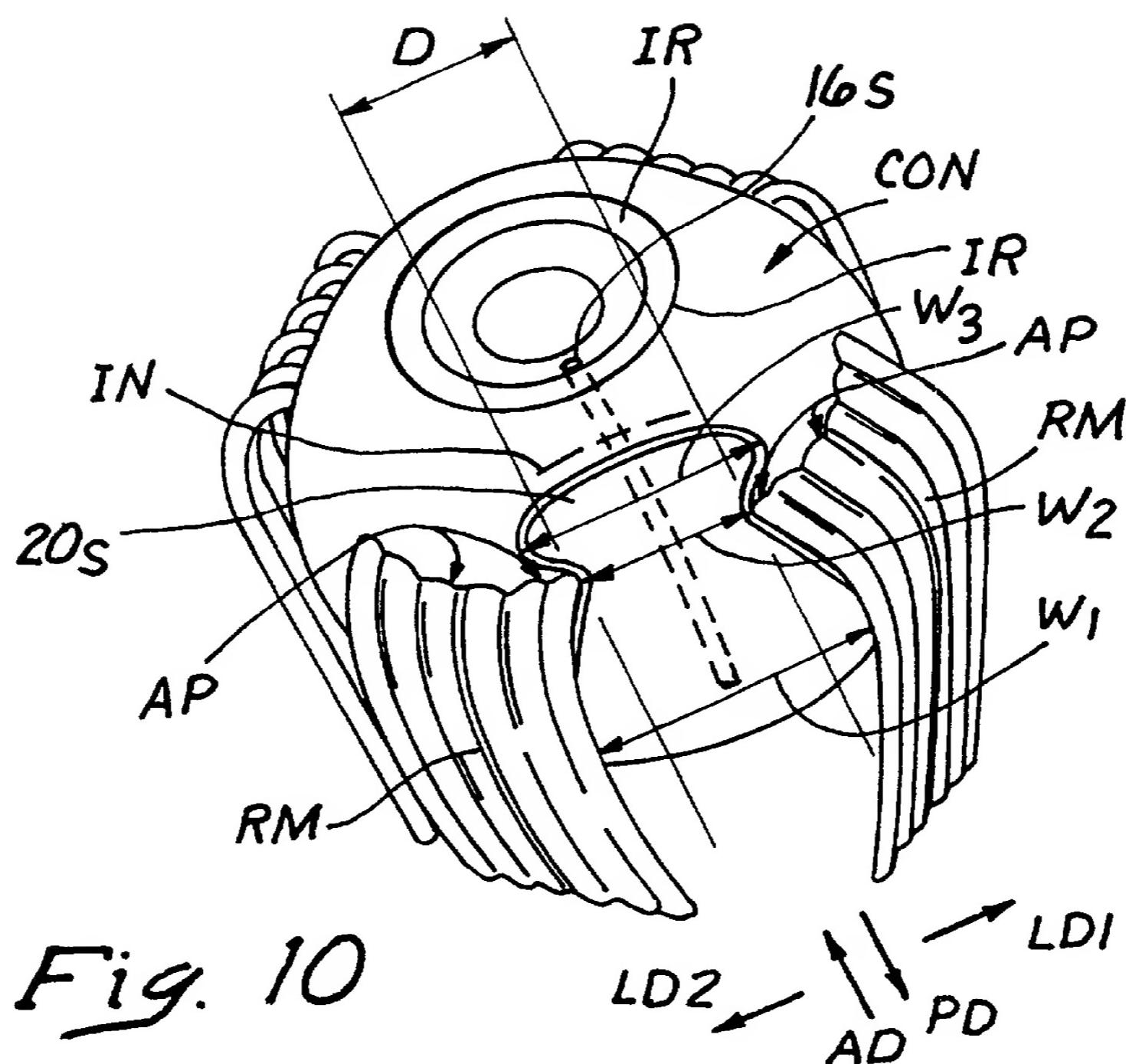
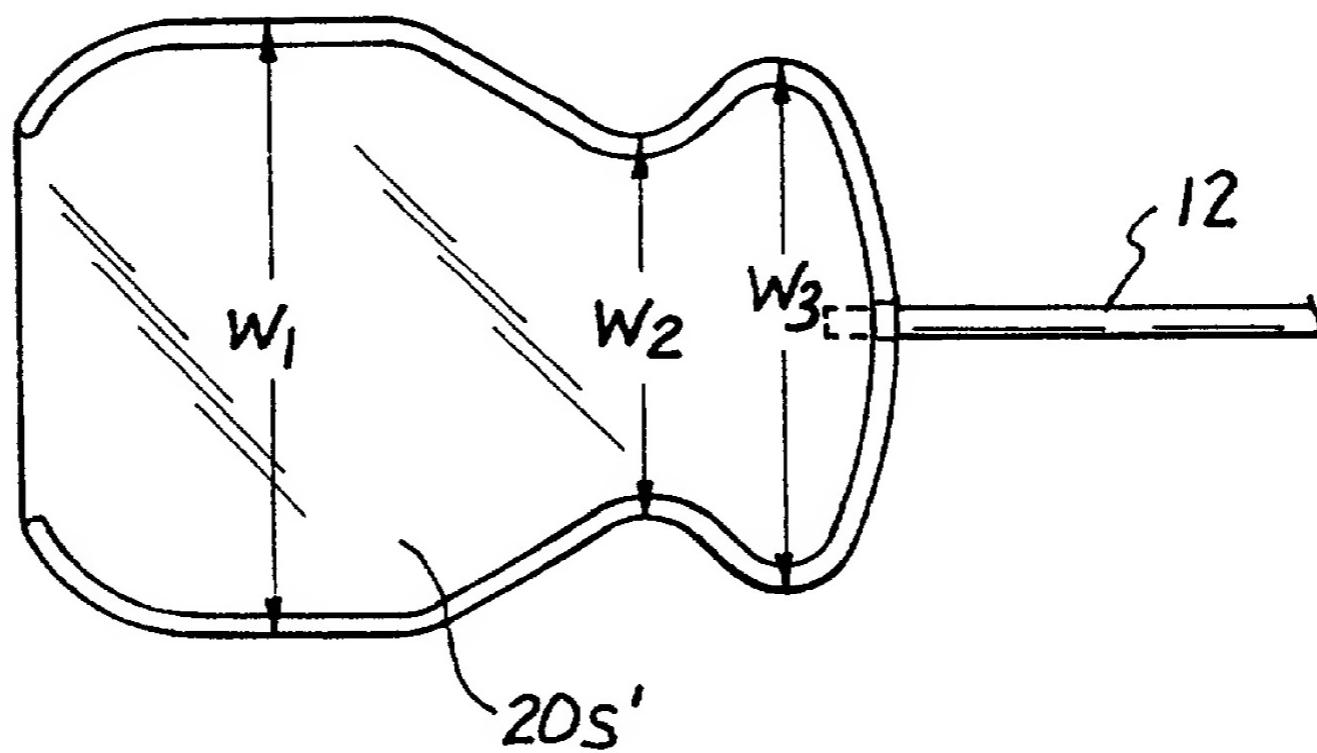


Fig. 10

Fig. 12



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CREATE INCISION AT LIMBUS

FORM SUBCONJUNCTIVAL POCKET  
POSTERIOR TO INCISION, BETWEEN  
AND POSTERIOR TO RECTUS MUSCLE  
ATTACHMENT LOCATIONS

INSERT NEEDLE PARALLEL TO IRIS  
TO FORM PENETRATION TRACT  
FROM SCLERAL SURFACE WITHIN  
SUBCONJUNCTIVAL POCKET INTO  
ANTERIOR CHAMBER

COLLAPSE AND INSERT DIFFUSION  
CHAMBER INTO SUBCONJUNCTIVAL  
POCKET AND DEPLOY TO NON-  
COLLAPSED STATE

PASS TUBE THROUGH PENETRATION  
TRACT AND INTO ANTERIOR  
CHAMBER

CLOSE INCISION LEAVING DEVICE  
IMPLANTED BUT NOT SUTURED  
BETWEEN THE RECTI MUSCLES

*Fig. 13*

**DECLARATION OF INVENTORSHIP and  
LIMITED POWER OF ATTORNEY**

As a below named inventor, I believe that I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the invention entitled "Sutureless Implantable Device and Method for Treatment of Glaucoma," which is described and claimed in Application No. Filed Herewith filed Filed Herewith or to be filed and for which a patent is sought. My residence, post office address and citizenship are as stated below next to my name.

I have reviewed and understand the contents of the above identified application, including the claims, as amended by any amendment referred to herein.

I acknowledge my duty under Title 37, Code of Federal Regulations § 1.56(a) to disclose information which is material to the patentability of the invention I am claiming.

■ I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application: 08/738,332, filed October 25, 1996, now Pending.

As a named inventor and until I assign my rights to the invention, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith on my behalf: STEVEN C. SEREBOFF, Reg. No. 37,035, ROBERT D. BUYAN, Reg. No. 32,460, and RIVA W. BICKEL, Reg. No. 34,777. Send correspondence and direct telephone calls to: Robert D. Buyan, SEREBOFF & BUYAN, LLP, 2600 Michelson Drive, Suite 770, Irvine, CA 92612; telephone 949/261-2252 x26, facsimile 949/261-2988, email: [rbuyan@iplawexperts.com](mailto:rbuyan@iplawexperts.com).

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application and any patent issuing thereon.

Nigam, Alok, of Trabuco Canyon, California, USA, a citizen of United States of America. Post office address: 21381 Birdhollow Drive, Trabuco Canyon, California 92679

Signature: Alok Nigam Date: 7/24/98